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Criteria Document for DDT (DDD, DDE)

Environmental Protection Agency

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INTRODUCTION

CRITERIA DOCUMENTS FOR TOXIC POLLUTANTS

Scientific rationale and criteria developed pursuant to Section 307(a) of the Federal Water Pollution Control Act, P. L. 92-500, 33 U.S.C. §§ 1251 et seq., (1972), for the development and establishment of effluent limitations for toxic substances are set forth in the following chapters.

Section 307(a)(2) states inter alia that a proposed effluent standard "...shall take into account the toxicity of the pollutant, its persistence, degradability, the usual or potential presence of the affected organisms in any water, the importance of the affected organisms and the nature and extent of the effect of the toxic pollutant on such organisms..." Thereafter, having considered these factors, the Administrator is to set an effluent standard for toxic pollutants which provides an ample margin of safety.

In the development of criteria which serve as both the basis and the goal for the establishment of effluent limits, reliance was placed on the toxicity data derived from laboratory studies on a range of organisms including invertebrate, vertebrate, and mammalian test species. These studies provided extensive acute and chronic toxicity data based on feeding experiments for a wide range of aquatic organisms and consumers of aquatic organisms. Environmental studies documenting bioaccumulation in the food web of the toxic material by the food chain organisms and bioconcentration by organisms directly from water provided an important component data base upon which criteria were derived. Appropriate human toxicity data and mammalian carcinogenic studies, where available, were used also in developing criteria.

Aquatic toxicity data generally are obtained by one of two basic methods, the static and flow-through bioassay. The more traditional static bioassay employs a tank in which the test organisms are living and to which a given concentraction of toxicant is added. Any water loss due to evaporation is made up by the addition of fresh water. The flow-through bioassay, which is a more recent development, reflects more nearly the natural conditions. Concentrations of toxic substances are constantly maintained and provide a more accurate test of sensitivity of aquatic species. Water in a flow-through test is replenished constantly through flushing. Comparative results using the static and flow-through bioassays demonstrate that flow-through data yield lower toxicity values for a pollutant than a static bioassay. This fact is demonstrated by comparative studies as discussed in the endrin document. However, most of the data available were developed using static bioassays.

Some toxic pollutants are extremely stable and degrade only slowly or form persistent degradation products. Those pollutants which degrade rapidly pose a less severe long-term hazard unless their entry to the environment is continuous. A parent compound, e.g., aldrin, may rapidly degrade or be altered to a more toxic form, i.e., dieldrin.

Bioconcentration of toxic pollutants is a significant consideration in the development of criterion. The rate and degree of accumulation in an animal and the rate of loss from the animal are factors that help define the potential magnitude of the pollution load problem. As an example, a pollutant which bioaccumulates presents a hazard both to aquatic systems and potentially to man or other carnivores associated with the ecosystem. To satisfactorily manage a persistent or non-degradable pollutant requires the maintenance of a ceiling for ambient levels in water which will afford protection to the food chain and the consumers of aquatic life (animals including humans). The body burden of toxic pollutants in fish or food chain organisms may have no outward effect on the species but will affect consumers of that food level. As an example, the brown pelican, when feeding on endrin-contaminate fish may die or suffer species depletion through reproductive impairment.

Data on toxic effects of pollutants are not available for all species that may be exposed to the toxic pollutant in these complex societies. Such data would be necessary to ensure protection of the most sensitive species. It is desirable to know the relative sensitivity of a wide variety of species in order to have a better estimate of the sensitivity of the untested, most sensitive species. Because such data are not available on all species, the range in sensitivity of a small number of tested species is used to provide a measure of the range of sensitivity of all species.

The natural aquatic environment includes many kinds and life stages of plants and animals that are intricately interrelated to form communities. Criteria are developed to protect these interrelationships and incorporate aquatic toxicity data for a phylogenetic cross section of organisms as well as species representative of wide geographic distribution. Chronic studies are an important consideration in establishing criteria and require studies of at least one generation, i.e., one reproductive cycle. Use of an application factor for persistent and bioaccumulated toxic pollutants represents consideration of a safety factor. As discussed in the National Academy of Science publication on water quality (p. 185 of the NAS/NAE Water Quality Criteria -- 1972, GPO-5501-00520), the use of an application factor of 0.01 when applied to acute toxic values is thought to provide an ample margin of safety for certain chlorinated hydrocarbon pesticides.

Ecological importance of an organism is dependent on the role the organism plays within the ecosystem and upon its relationship to the food chain within the aquatic community and to consumers of aquatic life, including man. Thus, toxicity data for the top carnivores in a given ecosystem, as well as economically important species such as trout, salmon, menhaden and shrimp are needed for the development of a protective criteria level. Toxicity data for organisms such as the stonefly and Daphnia are of equivalent importance since these organisms are a food base for higher consumers and are representative of invertebrate species found in most waters of the United States.

Invertebrate species, such as the stonefly and the Daphnia, are an indication of the integrity of the aquatic food chain and their presence may be the controlling factor for the abundance of economically and recreationally important predators such as trout, bass or pike. While these fish may not directly consume the Daphnia or stonefly or, in fact, even inhabit the same waters, these lower order organisms are representative of the food chain base supporting predators.

Criteria levels, by their nature, are developed to protect aquatic organisms and consumers of aquatic life from direct toxic effect when placed on contact with the toxic pollutants; and, to protect from a more insidious and even greater danger, e.g., chronic effects. Chronic effects take the form of reproductive failures or the poisoning of predators consuming food organisms which have bioaccumulated levels of toxic pollutants as in the case of the brown pelican and consuming endrin loaded fish (see Attachment D, Endrin), and a variety of other physiological effects as discussed in the various documents. Decreases in aquatic organisms or consumers of aquatic life not always are coupled to point source discharges of toxic pollutants at concentrations below acute toxic levels; however, the addition of toxic levels which are not acutely toxic can achieve the destruction or at least disruption of aquatic systems by causing reproduction of failure. Hence, the need for application factors. The relationships between discharges of toxic pollutants and effects on important organisms of economic and environmental importance and consumers of these organisms are well documented in the criteria documents.

An approach to criteria development is to provide ample protection of the test species on the assumption that the response of these species will be characteristic of other associated organisms in the aquatic environment. A number of species have been considered in establishing a criteria

Use of mammalian systems to determine the carcinogenic potential of toxicants found in water follows the same principle as use of aquatic organisms to determine toxicity to fish and other organisms. Carcinogenic substances pose a special hazard to man through environmental exposure. Cancer producing substances may reach man by several distinct pathways.

The following four criteria documents for aldrin/dieldrin, DDT and its metabolites, endrin and toxaphene, represent a survey of the scientific literature documenting the effects of these toxic pollutants to aquatic life and consumers of aquatic life including man. A glossary of terms is provided to define the terms used throughout the documents and will be expanded as necessary when additional documents are added.

DDT

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DDT

I. Preamble

DDT and its derivatives are among the most widely distributed synthetic chemicals on earth. They are found in soils, runoff water, air, rainwater, and in the tissues of animals. Basic characteristics of DDT include persistence, mobility, and a broad range of toxicological effects. These effects are discussed in Part II of this document, and have been reviewed at considerable length by the Agency and reviewing courts in the course of cancellation and suspension proceedings under the Federal Insecticide, gicide, and Rodenticide Act, as amended, 7 U.S.C. §135 et seq. (FIFRA). pertaining to registration, reregistration and classification procedures. For a full background of those proceedings, including the findings of toxicity and carcinogenicity (including the substantial risk of cancer with respect to human beings), the following materials are incorporated herein by reference, and attached hereto as appendices:

Document	Appendix
Consolidated DDT Hearings, Opinion, and Order of the Administrator of June 14, 1972. 37 F.R. 13369 (July 7, 1972).	A
Environmental Defense Fund v. *Environmental Protection Agency*, 489 F.2d 1247 (D.C. Cir. 1973).	B
Federal Register publication and preamble of Subpart D of the Environmental Protection Agency's ("EPA") Rules of Practice for Applications Under Sections 3 and 18 to Modify Previous Cancellation or Suspension Orders. 40 F.R. 12261 (March 18, 1975).	C

State of Louisiana Request for Emergency Use of DDT on Cotton: Statement of Reasons for the Order and Determination of the Administrator that Reconsideration of the Agency's Prior Order of Cancellation of DDT for Use on Cotton Is Not Warranted (March 17, 1975); Order and Determination of the Administrator that Reconsideration of the Agency's Prior Order of Cancellation of DDT for Use on Cotton Is Not Warranted (March 14, 1975); Supplement to the Order and Determination and Statement of Reasons for the Order and Determination of the Administrator that Reconsideration of the Agency's Prior Order of Cancellation of DDT for Use on Cotton Is Not Warranted (April 1, 1975). 40 F.R. 15934 (April 8, 1975). D

Federal Register

Preamble to Subpart Part A, Part 162, 40 CFR, of EPA's Regulations for the Enforcement of the Federal Insecticide, Fungicide, and Rodenticide Act, Pertaining to Registration, Preregistration and Classification Procedures, 40 F.R. 28242-28267 (July 3, 1975). E

By way of brief summary of the extensive proceedings and intense scrutiny of DDT and its properties set forth in the above-referenced materials, on October 31, 1969, the Environmental Defense Fund (EDF) and other environmental ups petitioned the Secretary of Agriculture, prior to the existence of EPA, to cancel the registration of all pesticide products containing DDT and to suspend those registrations pending cancellation proceedings because of its health hazards. In response to this petition, USDA cancelled uses of DDT on shade trees, tobacco, around the home, and in aquatic areas, and requested comments on other uses. Following litigation, the Secretary in June 1970, made further findings of toxicity of DDT to birds, bees, and fish.

Further litigation by EDF resulted in judicial remand of DDT proceedings to the EPA Administrator who, on January 15, 1971, issued cancellation notices for all remaining registrations of DDT products. On September 9, 1971, a committee of experts nominated by the National Academy of Sciences, following a lengthy investigation, reported that DDT posed an imminent hazard to the environment, and recommended that all DDT uses be rapidly phased out. Thereafter EPA held lengthy public hearings between August 17, 1971, and March 16, 1972, before a hearing examiner.

Following these hearings the Administrator on June 14, 1972, cancelled all DDT registrations except those for public health and agricultural pest quarantine use. See 37 F.R. 13369, (Appendix A).

In his decision the Administrator stated that he was "persuaded...that the long-range risks of continued use of DDT for use on cotton and most other crops is unacceptable and outweighs any benefits." 1972 Order, 37 F.R. 13369.

The Administrator found that "once dispersed, DDT is an uncontrollable, durable chemical that persists in the aquatic and terrestrial environments". 1972 Order, 37 F.R. 13370 par. III A. He concluded that DDT was "highly volatile" (37 F.R. 13370 n. 16) and is transported by drift during aerial application" as well as by runoff (Id., n. 13). He further found that, "Given its insolubility in water and its propensity to be stored in tissues, it collects in the food chain and is passed up to higher forms of aquatic and terrestrial life." (Id. at 13370, par. III, A, 1). The Administrator also found that DDT "can persist in the soils for years and even decades" (Id. at 13375, par. A, 1); that it "can persist in aquatic ecosystems" (Id. at 13375, par. II, A, 2); and that "it is occasionally found in remote areas or in ocean species, such as whales, far from any known area of application" (Id. at 13370-71). As a result of its persistence and mobility, the Administrator found that DDT is "concentrated in organisms and transferred through food webs" (Id. at 13375, par. III, A, 1); that DDT "accumulation in the food chain and crop residues results in human exposure" (Id. at 13375, par. III A, 2); and that

"Human beings store DDT" in their tissues (Id. at 13375, par. III, A, 3).

The Administrator also found that DDT poses hazards to birds, fish and other animal life:

"1. DDT affects phytoplankton species' composition and the natural balance in aquatic ecosystems.

2. DDT is lethal to many beneficial agricultural insects.

3. DDT can have lethal and sublethal effects on useful aquatic freshwater invertebrates, including arthropods and molluscs.

4. DDT is toxic to fish.

5. DDT can affect the reproductive success of fish.

6. DDT can have a variety of sublethal physiological and behavioral effects on fish.

7. Birds can mobilize lethal amounts of DDT residues.

8. DDT can cause thinning of bird eggshells and thus impair reproductive success." (_Id_. at 13375 IV, A, 1-8).

With respect to human health, the Administrator found that "DDT causes tumors in laboratory animals"; that "there is some indication of metastasis" of such tumors; that "tumor induction in mice is a valid warning of possible carcinogenic properties", and that there are "no adequate negative experimental studies in other mammalian species" and that for obvious reasons one cannot run experiments on an beings to gather such epidemiological data. Accordingly, the Administrator found that DDT poses a cancer risk to man. (_Id_. at 13375, par. IV, A, 9; IV, B).

The Administrator's cancellation order was upheld by the U.S. Court of Appeals for the District of Columbia Circuit in 1973 (Appendix B). Subsequently in the spring of 1975 the State of Louisiana requested reconsideration of the 1972 Order so as to permit emergency use of DDT on cotton. In denying that request, the Administrator found that scientific data gathered since the 1972 Order strengthened and confirmed the Agency's prior determination that DDT is highly toxic to a wide variety of animals and organisms, that it is highly persistent in the environment, that it poses a serious risk of cancer to man, and that humans and other organisms should not be subjected to the hazards posed by its further release into the environment. (Appendix D; See e.g. 40 F.R. 15939-15941, 15950).

Notwithstanding the cancellation of most uses of DDT under FIFRA, pesticides utilizing DDT will continue to be produced and formulated in this country as long as demand them continues in other parts of the world. Therefore, limits that protect all receiving water uses must be placed on concentrations of DDT in effluents of plants that produce and formulate these pesticides.

For the reasons hereinafter set forth a criterion of 0.001 ug/l for DDT is recommended. All human contact should be avoided, due to the demonstrated carcinogenic activity of DDT.

1.1. Chemical-Physical Properties

Dichlorodiphenyl trichloroethane (DDT: 2,2-bis-(p-chlorophenyl) - 1, 1, 1-trichloroethane) is a white crystalline powder with a melting point of 108.5 to 109° C, a boiling point of 185° C, a vapor pressure at 20° C of 1.9 X 10-7 mm mercury, and a low solubility in water (1 ug/l).

Since DDT is almost insoluble in water and is readily sorbed, it tends, in aquatic systems to associate with particulate material. DDT exhibits a strong affinity for fatty tissue and, when biologically consumed, accumulates in lipid fraction of aquatic organisms. Incorporation of DDT into aquatic organisms may occur from direct contact with DDT-containing water or through ingestion of particulate matter containing DDT (1). Buildup of DDT occurs between lower and higher members of the food chain resulting in increasing harm to fish and birds (2, 3).

A degradation of DDT to DDD (1, 1-dichloro-2, 2-bis (p-chlorophenyl) ethane) occurs in the anaerobic zones of aquatic systems (4, 5). A study in 1973 of the degradation of DDT in the anaerobic sediments was conducted by treating fields with DDT and then flooding. Before flooding, the soil rapidly became anaerobic (redox-potential dropping below -150 mV). The DDT concentration rapidly decreased from 8.1 ug/g to 0.5 to 1.6 ug/g with a concomitant increase in DDD concentration of from 0 to 4.2 to 5.6 ug/g. Rates of appearance of DDD and disappearance of DDT were slower in control plots not receiving the organic material, indicating that an anaerobic process was responsible for the conversion of DDT TO DDD which also can be transformed to DDE (10, 11). DDD, produced by the dechlorination of DDT, is also used in agriculture and differs only slightly in its toxicological perties and biological accumulation characteristics. DDE, produced by the dehydrochlorination of DDT, is closely related though not used in agriculture (34). Thus, for the purpose of this document the three compounds are considered collectively, and the references to DDT are applicable generally to DDD and DDE as well.

When DDT was applied at 10 to 20 lb/A, it was found in the soil from four (6) to ten (7) years later. When applied at a rate of 100 ppm (224 kg/ha to a depth of 38 cm) to sandy loam soil, 39 percent of the DDT remained after 17 years (8). Soil in a Maine forest treated with DDT at 1 lb/A showed little decrease in residues during the 9 years after application and the investigators suggest that residues may persist for 30 years (9). Once applied to soil, DDT migrates to water in association with suspended sediment (12).

III. Toxicological Data

Toxic effects resulting from the presence of DDT in water have been documented for aquatic organisms representing a wide phylogenetic cross section and geographic distribution. While all test organisms used may not be universally distributed in the waters of the United States, they represent types of organisms present in fresh, marine and estuarine systems throughout the country. Extrapolation from the effects found in laboratory and field tests is a reliable means for predicting effects of DDT on individual organisms and their food chains and is recognized as such by the scientific community.

It should be noted that the LC50 values reported for static tests are likely to be substantially higher than LC values found using flow-through bioassays. For instance, Earnest in 1970 (87) found a 96-hour TLm of 0.86 ug/l of DDT for Korean shrimp, Palaemon macrodactylus, using a static bioassay, and a TLm of 0.17 ug/l using an intermittent-flow bioassay. This may explain why Katz in 1961 (88) reported a 96-hour TLm of 11.5 ug/l for chinook salmon, Oncorhynchus tshawytscha, in fresh water, while Earnest calculated a value of 4.66 ug/l for the same species in an intermittent-flow bioassay. These data suggest loss of toxicant in static bioassays. Static tests in which dissolved oxygen and toxicant concentrations are measured periodically are more reliable than those in which these parameters are not monitored. The flow-through bioassays more accurately reflect nature, where "container wall" effects are likely to be negligible and where the volume of water per fish is much greater.

A. Microbes

There is a paucity of information on the effects of DDT on microbial systems. A study in 1974 indicated that the *Escherichia coli* and *Bacillus fragilis* when grown in a medium containing 10 ug of DDT exhibited differential responses. The *E. coli* strain yield was higher than in the controls while the *B. fragilis* yield was lower than in the controls. The formation of DDD was observed in both culture media (13).

B. Primary Producers

Reduction of photosynthetic activity has been reported to occur in the presence of DDT. Phytoplankton test cultures were exposed to different concentrations of DDT for 20 to 24 hours, with 14 hours of light and 10 hours of darkness. After this exposure period, C^{14} labeled bicarbonate was added and the algae illuminated for an additional 4 to 5 hours. The amount of carbon fixed by photosynthesis was determined by radio-assay of the filtered cultures. The effects of DDT exposures on photosynthesis were determined by comparison of the rate of photosynthesis of DDT-exposed and controlled populations. The phytoplankton populations exposed to levels as low as 100 ug/l fixed less CO than the control populations. This suggests that reductions in productivity at DDT concentrations as low as 100 ug/l may be expected (14).

C. Aquatic Invertebrates

Results of static bioassays conducted with DDT on various invertebrates are shown in Table 1 which relates exposure time and LC50 values for the invertebrate anisms. It can be seen that as exposure time increases sensitivity also increases.

TABLE 1

LC50 Values for Various Arthropods to DDT.

Arthropod Species	Exposure Time (hrs)	LC50 (ug/l)	Ref.
Scud (Gammarus lacustris)	24	4.7	16
" " "	48	2.1	16
" " "	96	1.0	16
Stonefly (Pteronarcys californica)	24	41.0	18
" " "	48	19.0	18
" " "	96	7.0	18
" (Pteronarcella badia)	24	12.0	18
" "	48	9.0	18
" " "	96	1.9	18
" (Claassenia sabulosa)	24	16.0	18
" " "	48	6.4	18
" " "	96	3.5	18

Gammarus lacustris is more sensitive to DDT stress as the ambient water temperature is increased. It has been demonstrated that as the temperature increases from 40°F to

70°F the 24-hour LC50 decreases from 12 ug/l to 4.7 ug/l (16).

Additional studies comparing the toxicity of DDT and of DDD to freshwater invertebrates are shown in Table 2.

Table 2

Comparison of the
96-hour LC50 of DDT and DDD
for Freshwater Crustaceans

Species	96-hour LC50 DDT	DDD	REF.
Gammarus lacustris	1.0	0.64	15
Gammarus fasciatus	0.8	0.86	15
Palaemonetes kadiakensis	2.3	0.68	15
Asellus brevicaudus	4.0	10.0	15
Orconectes nais	0.24	----	15

Marine invertebrates generally exhibit the same range of sensitivities to DDT as freshwater invertebrates, as seen in table 3.

Table 3

96-hour LC50 Static Bioassay for
Toxicity of DDT to Marine Invertebrates (85)

Species	LC50 (ug/l)
Sand shrimp (Crangon septemspinosa)	0.6
Grass shrimp (Palaemonetes pugio)	2.0
Hermit crab (Pagurus longicarpus)	6.0

A 28-day flow-through bioassay for the pink shrimp *Penaeus duorarum* resulted in a TL50 of 0.12 ug/l (76).

Fiddler crabs, *Uca pugilator*, fed plant detritus containing 10 ug/g DDT became disoriented and lost coordination and equilibrium (22).

D. Fish

The available data on fish demonstrate that DDT is toxic to many species. The sensitivity of fish and the hazards from disruption to their food chain by DDT have been known least since 1944 (24). The high toxicity of DDT to goldfish was described in 1944 (25) and deaths of young fish in waters sprayed with DDT were reported in 1946 (26).

The LC 50 values of DDT tested against various species of freshwater fish are shown in Table 4.

Table 4

Toxicity of DDT to Various Freshwater Fishes (27) (Static Bioassay)

Fish Species	LC50 ug/l
Largemouth bass (*Micropterus salmoides*)	2
Brown trout (*Salmo trutta*)	2
Coho salmon (*Oncorhynchus kisutch*)	4
Redear sunfish (*Lepomis microlophers*)	5
Black bullhead (*Ictalurus miloe*)	5
Rainbow trout (*Salmo gairdneri*)	7
Bluegill (*Lepomis macrochirus*)	8
Yellow perch (*Perca flavescens*)	9
Carp (*Cyprinus carpio*)	10
Channel catfish (*Ictalurus punctatus*)	16
Fathead minnow (*Pimephales promelas*)	19
Goldfish (*Carassius auratus*)	21

Cutthroat trout, *Salmo clarki*, were exposed in laboratory studies for 30 minutes once a month for one and one-half years to nominal DDT levels of 10 ug/l, 30 ug/l, 100 ug/l, 300 ug/l and 1,000 ug/l. At the end of the experiment period, from 50 to 75 percent of the 636 fish in each group were dead at the three highest concentrations of DDT (i.e., 1,000 ug/l, 300 ug/l and 100 ug/l). The number and volume of eggs produced by the trout were not reduced by these levels of DDT, but mortality among sacfry was higher at the 300 ug/l and 1,000 ug/l levels (28).

Some species of fish are extremely sensitive to DDT. r example, the extrapolated LD50 dosages for young chinook and coho salmon were 27.5 and 64 ug/kg/day, respectively. The chinook salmon, *Oncorhynchus tshawytscha*, appeared to be two to three times more sensitive to DDT than were coho salmon (29). When Atlantic croaker, *Micropogon undulatus*, were fed 2.75 ug of DDT per gram weight of fish per day for 67 days, the accumulated DDT resulted in mortality beginning on the 14th day and continuing until all fish were dead by the 67th day (30).

Acute toxicity values of DDT to some estuarine fish are seen in Table 5. Estuarine species exhibit sensitivities similar to those seen in freshwater species.

Table 5

Toxicity of DDT to Various Estuarine Fishes (84)

(Static Bioassay)

Test Species	96-hour LC50 ug/l
Mummichog (*Fundulus heteroclitus*)	5.0
Striped killifish (*Fundulus majalis*)	1.0
Atlantic silverside (*Menidia menidia*)	0.4
Striped mullet (*Mugil cephalus*)	0.9
American eel (*Anguilla rostrata*)	4.0
Bluehead (*Thalassoma bifasciatum*)	7.0

Sheepshead minnows, *Cyprinodon variegatus*, that survived DDT exposures which killed most of the fish tested, tended to have offspring more sensitive to DDT than those of the control group. Abortion of young was observed among mosquitofish, *Gambusia affinis*, that survived exposure to organochlorines at dosages that killed a portion of the group (35).

Fish survive relatively high DDT residues in their body fats, but residues concentrated in the eggs of mature fish may be lethal to the developing fry. Burdick in 1964 (33) reported up to 100 percent loss of lake trout fry, Salvelinus namaycush, when residues of DDT-DDD in the eggs exceeded 4750 ug/kg. Higher losses were not observed since experiments were terminated when mortality reached 50 percent.

DDT can adversely affect fish in an indirect manner by reducing or destroying important elements in the fish food supply (80).

E. Birds

A study of the acute oral toxicity of technical grade DDT to birds gave the results shown in Table 6 (36). The birds in this study were fed diets containing varying amounts of DDT for 5 days followed by 3 days of food containing DDT.

Table 6

Toxicity of DDT to Birds When Incorporated into Feed (36)

Bird	Weight (mean) (g)	5-day LC 50 (mg/kg of feed)
Blue Jay	72.8	415
House Sparrow	26.7	415
Cardinal	37.9	535
Bobwhite quail (wild)	143.8	1170
Bobwhite quail (farm)	202.4	1610

Six-week-old male and female broad-breasted white turkeys were fed diets containing 264.6 ppm (mg/kg) o, p' DDT or p, p' DDT for 7 or 15 weeks (37). This dosage did not cause any detectable alterations of blood pressure or gross tissue structure changes of the heart, aorta, liver, testes, oviduct, ovary, thyroid or kidney. In addition, no plasma changes were seen with regard to cholesterol, calcium levels, albumin-globulin ratio, or lipoprotein patterns.

A study in which DDT was administered to birds orally in gelatin capsules gave the LD50 values shown in Table 7 (38).

Table 7

Acute Oral Toxicity of DDT to Birds (38)

Bird	Sex	Age	LD50 (single dose) (mg/kg body wt.)
Mallards	F	3 months	2240
Pheasants	F	3-4 months	1296
European quail	M	2 months	841
Pigeons	M&F	-------	> 4000
Lesser Sandhill Cranes	M&F	Adult	> 1200

The 30-day mean lethal dose for mallards was 50 mg/kg/day. Adult mallards fed 100 ppm DDT in the diet showed a median survival time of about one year. In a 90-day feeding study, 30 ppm DDT in the diet was not lethal to either mallards or bobwhite quail.

DDT does not appear to be significant in the acute poisoning of bird species because of the large dosages required to cause death. While acute toxicity is not likely to be significant, there is considerable evidence to suggest that DDT decreases the reproductive capacity of some bird species. Studies were made of mallard ducks' reproductive ability as a function of dietary DDT, DDD, and DDE (39). DDT at the 25 ppm dietary level induced thinning of shells and reduced duckling survival. DDD, however, did not interfere with reproduction. A DDT-DDE mixture (20 ppm each) in the diet caused eggshell thinning and increased embryo mortality (39).

F. Mammals

The acute toxicity of DDT to mammals is low. Animal experimentation conducted over 20 years ago established that the median lethal dose of DDT by the oral route in mg/kg body weight is 150 to 250 for mice and rats, 150 to 300 for cats and dogs, 300 to 500 for guinea pigs and rabbits, over 200 for monkeys, over 300 for cows and horses, and 1,000 for sheep and goats (40). All subsequent experimentation and use experience has confirmed the early finding of low mammalian acute toxicity of DDT.

In an experiment in 1972, squirrel monkeys, *Siomuri sciureus*, were fed p, p' DDT in peanut oil at levels of 50, 5, 0.5, 0.05 and 0 mg/kg body weight/day (43). The animals that were fed 50 mg/kg body weight/day exhibited initial clinical signs of toxicity (staggering, weight loss, weakness, and loss of equilibrium). After the initial toxicity symptoms in the group fed 50 mg/kg/day, the monkeys began to recover. However, during the fourth week, four of the experimental animals in the high dose group died. The remaining two monkeys died during the 9th and 14th week of the experiment. None of the monkeys fed 5 mg/kg/day of DDT died as a result of DDT intoxication. Some were sacrificed intervals and no discernible effects on hematological values of plasma enzyme levels appeared.

A study employing albino rats determined the 24-hour LD 50 of technical grade DDT to be 118.7 mg/kg of body weight. The chronic effect of 100 ppm DDT in the diet was also investigated for a 6-month period. The 100 ppm level did not adversely affect the mortality rate and growth of the rats. No changes in physical behavior were noted. The only significant effects were an increase in liver weight and a shortening of the pentabarbitone-induced sleeping time in the DDT fed rats (44).

New Zealand white rabbits were fed DDT in corn oil at the rate of 50 mg/kg/day during the seventh, eighth, and ninth day of gestation. Fifty-seven percent of the treated rabbits delivered prematurely (less than 28 days of gestation). DDT increased the number of resorption sites, and the weight of fetuses from the DDT-fed rabbits was significantly lower. None of the control animals delivered prior to 30 days of gestation. The same levels of DDT fed on days 22 and 23 of gestation showed no effects (45).

A dose of 12 mg/kg daily in beagle dogs resulted in subnormal reproductive activity. It was concluded from these results that the feeding of DDT induced lasting metabolic changes reflected in delayed estrus, reduction of libido, stillbirths and lack of mammary development with reduced milk production which was responsible for a high mortality rate among the offspring (48, 49).

Genetic damage has also been shown to result from DDT ingestion. The administration of 100 to 400 ppm in the diet of mice resulted in an increased incidence of chromosomal abnormalities in the form of deletions, stickiness, and rarely, ring and metacentric chromosomes (50). This study indicated that chromosomal damage to mice occurred frequently at dosages of 150 ppm or higher (LD50 is 550 ppm). Since the induction of chromosomal damage is often associated with mutagenic occurrences in mammals, DDT is a potential mutagen. Further evidence of the mutagenic potential comes from *in vitro* studies on cell lines derived from the kangaroo rat, where concentrations as low as 10 'l of p, p' - isomers of DDT, DDD and DDE in the medium caused some damage in the cells (51).

In a study in 1965 of the carcinogenicity of 130 pesticides and related compounds including DDT, it was found that DDT significantly increased the incidence of hepatomas in two strains of mice. When p, p' DDT was administered by gavage (i.e. stomach tube) at a dose of 46.4 mg/kg of body weight and at a level of 140 ppm in the diet (140 mg/kg food), the incidence of hepatomas in 36 treated males was 50 percent, and 14 percent in 36 treated females. The non-treated controls exhibited a 7 percent incidence for a group of 169 animals, both male and female (46).

Studies were undertaken to determine the effect of DDT exposure over several generations. Mice (BALD/c strain) were fed 2.8 to 3 ppm DDT for six months and observed for an additional 20 months. A progressive increase in tumors from the second generation onward was seen. In the test group of 684 mice, tumors developed at an incidence greater than in the control group. The DDT-fed group showed a greater incidence of leukemia and malignant tumors than the controls the F^1 and F^2 generations with increasing incidence in later generations (52). The accumulated DDT content in the fatty tissue of the experimental group amounted to 7 to 11 mg/kg.

It is extremely sigificant to note that the value for concentrations of DDT in the fatty tissue of mice is on the same order as the DDT levels in the fatty tissue of urban populations of human beings (53).

In a definitive study by Tomatis et al. in 1972, using a second strain of mice (CF-1) given DDT in the diet at concentrations of 2, 10, 50 and 250 ppm for the entire life span for two consecutive generations, hepatic tumors developed at all concentrations in the male populations. Female populations exhibited a slight increase in numbers of hepatic tumors following exposure to 10 and 50 ppm with a marked increase at the 250 ppm concentration. The age at death with liver tumors and the incidence of liver tumors was DDT-dose-related in the exposed mice (54). These results support earlier findings which used p, p' DDT on still another strain of mice (46).

In November 1973 a team of Russian scientists reported the results of a multi-generation DDT feeding study in which two groups of A-strain mice were fed 10 and 50 ppm DDT in the parent generation while five succeeding generations were fed 10 ppm. DDT caused a significant increase in lung tumors at both feeding levels in the parent groups. All of the five succeeding generations showed an increase in lung tumors over control animals; the increase was significant statistically in the second, third and fourth generations fed 10 ppm, the only dose so tested (90). The finding that DDT induced carcinogenicity at a site other than the liver supports the results of an earlier report by a Hungarian team which showed DDT to cause a progressively significant increase in leukemia and other malignant tumors at several different sites in the second through the fifth generations of mice fed approximately 3 ppm of DDT in the diet (52).

In March 1974 the first study of the effects of the long-term feeding of p,p' DDE, the principal DDT metabolite found in all humans and in the highest quantity of all of e metabolites, was reported. At the only feeding level tested (250 ppm), p,p' DDE was shown to be an extremely potent liver carcinogen in both male and female mice, but particularly in females in which there was a 98% incidence of tumors compared to only 1% in the control animals. Another DDT metabolite, p,p' DDD fed at the same single feeding level caused a significant increase in lung tumors (91).

G. Human Health Hazard

Very few cases of acute DDT poisoning have occurred in man and there is no well-documented case of fatal DDT poisoning.

The pharamacological effects of oral doses of DDT in man have been studied. There are some differences in the doses reported to produce various effects, but the types of changes and their duration were the same in all studies. The lowest oral doses of DDT reported to produce effects in man were those used by Velhinger (42). In that study, oral ses of 250 or 500 mg per man in suspension or oil solution produced no effect except a variable, slight disturbance of the sensitivity of the mouth. Doses of 750 or 1000 mg in solution led to disturbances of the sensitivity of the lower part of the face, uncertainty of gait, malaise, hypersensitivity to contact, cool moist skin, but no changes in reflexes. Discomfort reached a peak in about 6 hours. A dose of 1500 mg in oil solution produced prickling of the tongue beginning about 2.5 hours after ingestion. Disturbance of equilibrium, dizziness, confusion and tremors the extremities gradually increased. A peak reaction characterized by malaise, headache, fatigue, and delayed vomiting was reached about 10 hours after ingestion and recovery was almost complete in 24 hours.

As previously discussed, experimentation with mammals has led to the conclusion that DDT poses a substantial human health hazard.

In 1972, former EPA Administrator Ruckelshaus made the ctual finding that "DDT is a potential human carcinogen." As the basis for this finding the Administrator cited the fact that: "Laboratory tests have...produced tumorigenic effects on mice when DDT was fed to them at high levels" (Appendix D). The laboratory tests referred to were cited as the Bionetics study in which mice were fed 140 ppm of DDT and the Lyons study (at that time incomplete and still in progress) in which "increased hepatomas (liver tumors) were noted in male and female mice fed DDT at 250 ppm."

Nearly five months after the 1972 Order and some nine months after the close of the DDT hearing, the first final report of the Lyons study, referred to as "still in progress" in the 1972 Order, was published. That report not only showed DDT to cause a significant increase in liver tumors in the first generation of mice fed 250 ppm DDT, as noted in the 1972 Order, but also revealed that a similar significant increase in liver tumors was shown in two generations of male mice fed 50 ppm, 10 ppm and 2 ppm, the lowest known dosage of DDT ever tested (54).

In September of 1973, the final results of the Lyon study, extended to six full generations of mice (nearly ,000 animals) fed DDT at 2, 10, 50, and 250 ppm levels, were published. The findings in the succeeding four generations of mice confirmed the results reported in October 1972 in the parent and first generation treatment group. In the male mice in all six generations DDT caused a significant increase in liver cancer at every treatment level including 2 ppm, the lowest dosage tested (92).

Environmental Fate and Effects

Once dispersed, DDT is an uncontrollable, durable chemical that persists in the aquatic and terrestrial environments. It can evaporate from crops and soils and can be transported adsorbed to eroding soil particles. DDT can persist in the soil and in aquatic ecosystems and is occasionally found in areas or in biota far from any known area of application. As a result of its persistence and mobility DDT accumulates in the food chain and crop residues resulting in exposure of humans who also store DDT in their tissues (Appendix A).

Movement of DDT into the aquatic ecosystem is critical since, once in water, this pesticide is persistent and remains toxic. Entrance into water may be accomplished by physical, chemical or biological transport. It is virtually impossible to identify all the various physical factors acting upon persistent organic chemicals such as DDT (56). However atmospheric transport (55) and washing of contaminated soils would be the most frequent routes.

The relatively low solubility of DDT in water and its high lipid solubility tend to allow for removal from the water column by accumulation in plant and animal fats. Once applied to soil, DDT migrates to water (12). It is very stable, and its vapor pressure results in loss to the atmosphere allowing for atmospheric transport (57).

DDT accumulates in sediments, living organisms and particulate matter. Eventually, the DDT tends to reach the water surface where it will co-distill with water to again enter the atmospheric cycle. When in air and exposed to ultraviolet light in the region of 290 to 310 nanometers, it will convert to DDD and to DDE. After 4 days of irradiation, as much as 48 percent of DDT will convert to DDE and 2 percent to DDD (58).

Bioaccumulation of DDT begins at the very lowest trophic level. Yeast cells have been shown to take up DDT (59, 60). Subsequently fungi and bacteria, including species of *Streptomycetes*, *Bacillus*, *Serratea* and *Agrobacterium* have been shown to bioaccumulate this pesticide (59). The phytoplankter, *Chlorella*, has been shown to accumulate DDT from water (60). Thus both microbial populations and phytoplankton, the very basis of all food webs and hence among the most important organisms to be protected, initiate the bioaccumulation process of DDT.

Use of DDT at 100 ug/l for control of black flies in Labrador resulted in faunal changes. Caddisfly larval populations were reduced to zero or near zero at all stations receiving the treatment, and the same was true for stonefly and mayfly larva. The DDT also caused mortalities in eastern brook trout, *Salvelinus fontinalis*, by contamination of fish foods above maximum tolerance levels. No significant short-term fish mortality due to direct ntact was observed (21).

Bioaccumulation of DDT in higher life forms is better documented than for microbial species. Invertebrates have been shown to accumulate DDT some 70,000 times the level in water. The oyster, when placed in flowing sea water containing 0.1 ug/l will concentrate DDT up to 70,000 times in its tissue after 40 days (63). The hooked mussel, *Brachidontes recurvis* and the hard shell clam, *Mercenaria mercenaria*, both have been shown to accumulate DDT at factors of 1,260 times from 0.1 ug/l to 6,000 times from 1 ug/l respectively (63, 64).

Male and female lobsters, Homarus americanus, accumulate DDT in their flesh. Females also accumulate DDT in their egg masses. The concentration found in the flesh of untreated lobsters was 1 ppm, which represents a 10- to 100-fold concentration factor above that of their natural sea water (65). The pink shrimp, Penaeus duorarum, has been shown to effect a 1,500-fold concentration of DDT in three weeks when the water concentration was 0.14 ug/l (76).

Residues of DDT were found to reach a level of more than 13 lb/A in a Long Island saltmarsh. In sampling of the marsh and the organisms present in the water, the concentration of DDT was estimated to be 0.05 ug/l in the water, while in plankton the level was 40 ppb. The highest concentrations were detected in the scavenging and carnivorous fish and birds. The birds were reported to have 10 to 100 times higher DDT levels than the fish (67). When applied directly to estuarine waters, DDT has been shown to be rapidly absorbed by phytoplankton. It was observed that residues in the food web increased from a level of 1 ppb in water to 70 ppb in phytoplankton, 15,000 ppb in fish and 800,000 ppb in the porpoise (14).

Samples removed from a tidal marsh habitat in Florida treated with 0.2 lb/A of DDT were found to contain the following levels: surface water and ditch, 0.3 to 4.0 ppm; sediment samples, up to 3.35 ppm (dry weight); vegetation, up to 75 ppm (dry weight); and in fish, levels ranged from 4 to 89 ppm (wet weight) (69).

Sediments in Lake Michigan, on a wet weight basis, have .n found to average 14 ppb DDT and DDE. Examination of the amphipod, Pontoporeia affinis, in Lake Michigan for DDT levels demonstrated a concentration of 410 ppb DDT and its metabolites, i.e. a 30-fold concentration factor. Fish removed from the lake had levels up to 10 times that found in the amphipod while breast muscle from gulls averaged 27 times that of the lake alewives. The gull fat had a concentration of 2,441 ppm DDT (3). Subsequent studies on DDT levels in lake trout, Salvelinus namaycush, taken from southern Lake Michigan from 1966-1970 averaged 18.1 ppm in fish 55.8 to 68.4 cm long. Lake trout, *S. namaycush*, taken from Lakes Erie (2.2 ppm) and Superior (4.4 ppm) generally had lower levels of DDT in their flesh (70).

In the laboratory, rainbow trout, *Salmo gairdneri*, were found to accumulate greater amounts of DDT with an increase in temperature. When exposed to a concentration of .13 - .17 ppb DDT, levels of 37,600, 59,300 and 68,200 ppb were found in the fish at temperatures of 5°C, 10°C, and 15°C, respectively (71). In ponds containing 20 ug/l DDT, rainbow trout, *S. gairdneri*, black bullhead, *Ictalurus miloe*, and crayfish, *Orconectes nais*, were found to accumulate DDT to els of 4150 ppb, 3110 ppb and 1470 ppb respectively (68).

Studies using brook trout, *Salvelinus fontinalis*, have shown that a major source for accumulation of DDT can be the food web rather than uptake from water (72). Thus the fact that the amphipod, *Daphnia magna*, can concentrate DDT 16,000 to 23,000 times in water within 24 hours is important (73).

In an effort to precisely determine the fate of DDT, DDD and DDE in an ecosystem, a laboratory model was constructed utilizing a terrestial-aquatic interface and a seven-element food chain. Addition of DDT to the system simulated an air application rate to land of 1 lb per acre. It was found that DDT was accumulated in mosquito larva, snails and fish as either DDT, DDD or DDE at factors ranging from 10,000 to 100,000 (74). Hence DDT and its toxic metabolites have been shown to accumulate in aquatic food chain organisms, thus becoming available to higher carnivores and man.

V. Criteria Formulation

A criterion of 0.001 ug/l is recommended for protection of aquatic life.

DDT in water has been shown to be acutely toxic to aquatic invertebrates at 0.12 ug/l (84). DDT also has been observed to accumulate in fish tissue to levels two million times those of the ambient water (77). Mice exposed to 2 mg/kg of DDT in their feed (the lowest dose tested) developed hepatic tumors (46). Recognizing that 2 mg/kg of DDT in a diet has been demonstrated to cause tumors in mice, the concentration of DDT in aquatic organims should be less than 2 mg/kg to protect consumers of aquatic organisms. Since bioaccumulation by factors as high as two million has been demonstrated (77), a level of .001 ug/l in water could produce concentrations as high as 2 mg/kg in fish flesh. Thus, even at a water concentration of .001 ug/l some adverse effects might be expected among animals preying on aquatic organisms.

The 28-day LC50 for the pink shrimp, *Penaeus duorarum*, was reported to be 0.12 ug/l (84). Use of an application factor of 0.01 to assure the safety of this species and any others which may be equally sensitive, results in a criterion of 0.001 ug/l for the protection of aquatic life.

In man, tissue concentrations can reach levels which threaten adverse physiological reactions (42), including the potential for carcinogenesis. Since there is no demonstrated "no effect" level for carcinogens, and in light of the bioaccumulation potential of DDT, all human exposure should be avoided.

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GLOSSARY

Acutely toxic: Causing death or severe damage to an organism by poisoning during a brief exposure period, normally ninety-six hours or less.

Anadromous fishes: Fishes that spend a part of their lives in seas or lakes, but ascend rivers and streams at certain intervals to spawn. Examples are sturgeon, shad, salmon, trout, and striped bass.

Application factor: The ratio of the safe concentration to the lethal concentration as determined for potential aquatic pollutants administered to species of interest.

Bioaccumulation (Bioconcentration): The phenomenon wherein elements or compounds are stored in living organisms because elimination fails to match intake.

Carcinogenic: Producing Cancer.

Catadromous fishes: Fishes that feed and grow in fresh water, but return to the sea to spawn. The best example is the American eel.

Chronically toxic: Causing death or damage to an organism by poisoning during prolonged exposure, which, depending on the organism tested and the test conditions and purposes, may range from several days, to weeks, months, or years, or through a reproductive cycle.

EC50: The concentration at which a specified effect is observed under the test conditions in a specified time in fifty percent of the organisms tested. Examples of specified effects are hemorrhaging, decreased feeding, dilation of pupils, and altered swimming patterns.

Epilimnion: That region of a body of water that extends from the surface to the top of the thermocline and does not have a permanent temperature stratification.

Flow-through bioassay: An assay system in which aquatic species are exposed to toxicants in a constantly flowing system, and where the toxicant is replenished continuously or discontinuously.

Hardness (Water): The concentration of the polyvalent metallic ions dissolved in water. Unually it is reported as the equivalent concentration of calcium carbonate ($CaCO_3$).

Hyperplasia: Abnormal multiplication or increase in the number of normal cells in normal arrangement in a tissue.

Hypolimnion: The region of a body of water that extends from the bottom of the thermocline to the bottom of the water body and is essentially independent of most surface phenomena.

LC25: The concentration of a toxicant that is lethal (fatal) to twenty-five percent of the organisms tested under the test conditions in a specified time.

LC50: The concentration of a toxicant which is lethal (fatal) to fifty percent of the organisms tested under the test conditions in a specified time. It is virtually identical with TLm and TL50.

LD50: The dose of a toxicant that is lethal (fatal) to fifty percent of the organisms tested under the test conditions in a specified time. A dose is the quantity actually administered to the organism and is not identical with a concentration, which is the amount of toxicant in a unit of test medium rather than the amount ingested by or administered to the organism.

Liter (l): The volume occupied by one kilogram of water at a pressure of 760 mm of mercury and a temperature of 4° C. A liter is 1.057 quart.

Methylmercury: Mercury which has been methylated, usually through some biological agent, such as bacteria.

Microgram per liter (ug/l): The concentration at which one millionth of a gram (one microgram) is contained in a volume of one liter. Where the density of solvent is equal to one, one ug/l is equivalent to one part per billion (ppb) or one microgram per kilogram (ug/kg).

Microgram per kilogram (ug/kg): The concentration at which one millionth of a gram (one microgram) is contained in a mass of one kilogram. A kilogram is 2.2046 pounds.

Milligram per kilogram (mg/kg): The concentration at which one thousandth of a gram (one milligram) is contained in a mass of one kilogram. A gram contains 1000 milligrams.

Milligram per liter (mg/l): The concentration at which one milligram is contained in a volume of one liter. Where the density of the solvent is equal to one, one mg/l is equivalent to one part per million (ppm) or one milligram per kilogram (mg/kg).

Milliliter (ml): A volume equal to one thousandth of a liter.

Nanogram per liter (ng/l): The concentration at which one billionth of a gram (one nanogram) is contained in a volume of one liter. Where the density of the solvent is equal to one, one ng/l is equivalent to one part per trillion or one nanogram per kilogram (ng/kg).

Neoplastic: Describing any new and abnormal growth, such as a tumor.

Part per million (ppm): A concentration in which one unit is contained in a total of a million units. Any units may be used (e.g., weight, volume) but in any given application identical units must be used (e.g., grams per million grams or liters per million liters). Where the density of the solvent is one, one part per million is equivalent to one milligram per liter.

Parts per thousand (o/oo): A concentration at which one unit is contained in a total of a thousand units. The rules for using this term are the same as those for parts per million. Normally, this term is used to specify the salinity of estuarine or sea waters.

Piscicide: A substance used for killing fish.

Static bioassay: A bioassay in which the toxicant is not renewed during the test.

Thermocline: That layer in a body of water where the temperature difference is greatest per unit of depth. It is the layer in which the drop in temperature is 1 °C. or greater per meter of depth.

TLm - Median Tolerance Limit: The concentration of a test material at which fifty percent of the test animals are able to survive under test conditions for a specified period of exposure. It is virtually synonymous with LC50 and TL50.

TL50: Synonymous with TLm and virtually synonymous with LC50.

Tumorigenic: Causing or producing tumors.

APPENDIX A

ENVIRONMENTAL PROTECTION AGENCY

[I. F. & R. Dockets Nos. 63, etc.]

CONSOLIDATED DDT HEARINGS

Opinion and Order of the Administrator

Published herewith is my opinion and order issued June 14, 1972, concerning the registrations of products containing the insecticide DDT.

Done this 30th day of June 1972.

WILLIAM D. RUCKELSHAUS,
Administrator.

STEVENS INDUSTRIES, INC., ET AL.

OPINION OF THE ADMINISTRATOR

Before the Environmental Protection Agency: In re: Stevens Industries, Inc., et al. (Consolidated DDT Hearings), I.F. & R. Docket No. 63 et al.

This hearing represents the culmination of approximately 3 years of intensive administrative inquiry into the uses of DDT. Part I sets forth the background of these proceedings and Part II contains a discussion of the evidence and law and my factual conclusions. I am persuaded for reasons set forth in Part III of this opinion that the long-range risks of continued use of DDT for use on cotton and most other crops is unacceptable and outweighs any benefits. Cancellation for all uses of DDT for crop production and nonhealth purposes is hereby reaffirmed and will become effective December 31, 1972, in accordance with Part V of this opinion and the accompanying order, except that certain uses, for green peppers, onions, and sweet potatoes in storage may continue on terms and conditions set forth in Part V of this opinion and the accompanying order.

I—A. *Background.* DDT is the familiar abbreviation for the chemical (1,1,1,trichlorophenyl ethane), which was for many years the most widely used chemical pesticide in this country. DDT's insecticidal properties were originally discovered, apparently by accident, in 1939, and during World War II it was used extensively for typhus control. Since 1945, DDT has been used for general control of mosquitoes, boll weevil infestation in cotton-growing areas, and a variety of other uses. Peak use of DDT occurred at the end of the 1950's and present domestic use of DDT in various formulations has been estimated at 6,000 tons per year.[1] According to Admission 7 of the record, approximately 86 percent or 10,277,258 pounds of domestically used DDT is applied to cotton crops. The same admission indicates that 603,053 pounds and 937,901 pounds, or approximately 5 percent and 8 percent of the total formulated by 27 of the petitioners in these hearings are used respectively on soybean and peanut crops. All other uses of the 11,966,196 pounds amount to 158,833 of the total, or little over 1 percent.[2]

Counsel for the Agency has called to our attention publication of the Department of Agriculture, The Pesticide Review of 1971, which estimates "a domestic disappearance" rate of 25,457,000 pounds for DDT in 1970. See p. 28. The motion to incorporate this publication is granted, as is the motion by registrants to supplement the record, see infra. I do not believe, however, that the Pesticide Review figure can be accepted, on its face, without further explanation. Since the result I reach today would, if anything, only be reinforced by the higher figure, I see no need to remand.

For the above uses it appears that DDT is sold in four different formulations: Emulsifiable sprays; dust; wettable powder; and granular form.

Public concern over the widespread use of pesticides was stirred by Rachel Carson's book, "Silent Spring," and a natural outgrowth was the investigation of this popular and widely sprayed chemical. DDT, which for many years had been used with apparent safety, was, the critics alleged, a highly dangerous substance which killed beneficial insects, upset the natural ecological balance, and collected in the food chain, thus posing a hazard to man, and other forms of advanced aquatic and avian life. In 1969, the U.S. Department of Agriculture commenced a review of the health and environmental hazards attendant to the use of DDT.

Certain uses of DDT were canceled by the Department of Agriculture in 1969 and informal review of remaining uses continued through 1970.[3] In early 1971, this Agency commenced formal administrative review of DDT registrations by the cancellation of all registrations for DDT products and uses pursuant to section 4(c) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 7 U.S.C. section 135 (1972).[4]

B. *Statement of the case.* This hearing is the final stage of formal administrative review.[5] Thirty-one registrants have challenged 15 of the canceled uses of DDT and its metabolite, TDE.[6] These uses of DDT include applications to cotton fields to control the boll weevil and bollworm applications to various vegetable crops, and a variety of lesser uses in public programs. The case for cancellation has been presented by counsel for the Pesticides Office of the Environmental Protection Agency and attorneys for the Environmental Defense Fund which is an intervenor. Other parties include Eli Lilly & Co., which held a DDT registration for "opocide," a prescription drug,[7] H. P. Cannon & Son, a user of DDT,[8] and representatives of the chemical manufacturing industry and various wildlife groups.[9]

The testimony and exhibits cover in exhaustive fashion all aspects of DDT's chemical and toxicological properties. The evidence of record, however, is not so extensive concerning the benefits from using DDT, and most of it has been directed to the major use, which is on cotton crops.[10]

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[1] Admission 6 shows that domestic shipments of DDT by its sole manufacturer, Montrose Chemical Co., totaled 8,327,900 pounds between January 1 and August 1, 1971. Total domestic sales in 1970 were 11,966,196, as stipulated in Admission No. 7. The Examiner found, apparently based on Admission 7, that domestic use in 1970 "was just under 12 million pounds." Exam. Report at 92.

[2] Some discrepancy in the figures exists since the figures given in breakdown of use categories total 11,977,065 pounds, slightly more than the total sold by the 27 formulators who supplied figures.

[3] PR Notice 69–17. Among the canceled uses were applications to trees for control of Dutch Elm disease, tobacco, home uses, and aquatic uses. 34 F.R. 18827 (1969).

[4] In Environmental Defense Fund v. Ruckelshaus, 439 F. 2d 584 (D.C. Cir. 1971), the court of appeals held that cancellation proceedings should be commenced whenever a registration of a pesticide raises a "substantial question of safety" which warrants further study. On Jan. 15, 1971, all uses of DDT not canceled in 1969 were canceled. PR Notice 71–1. And on Mar. 18, 1971, notices of cancellation were issued for all registered uses of TDE, a DDT metabolite. PR Notice 71–5.

[5] Under FIFRA a registrant is entitled to either a public hearing or a scientific advisory committee or both to review his registration. Pending completion of that review, a registrant is allowed to continue shipment of his product.

[6] Unless specified, discussion of DDT in this opinion applies to TDE. DDT has three major breakdown products, DDA, DDE, and DDD; separate registrations exist for TDE (DDE).

[7] There has been some controversy over Eli Lilly's status because it failed to appeal cancellation of its registration within 30 days as required by section 4(c) of FIFRA. For the purposes of this case I believe they should be accorded status as parties.

[8] There has been some question as to whether or not a "user" has standing to appeal a cancellation and thus seek reinstatement of a canceled use even though no registrant has stepped forward to appeal. The same reasoning employed by the court in Environmental Defense Fund v. Ruckelshaus, supra, and Environmental Defense Fund v. Hardin, 428 F. 2d 1093 (D.C. Cir. 1970), which accords standing to "public interest" groups gives "users" a right to appeal a cancellation.

[9] The groups are: National Agricultural Chemicals Association; National Audubon Society; The Sierra Club; and West Michigan Environmental Action Council. As already noted, the Secretary of Agriculture, in addition to being a party-registrant by virtue of registrations held by its Plant Regulation Division, has appeared as an intervenor.

[10] The following uses are involved: For cotton; for military use on clothing; for peppers and pimentos; for fresh market corn; for peanuts; for cabbage, cauliflower, and brussel sprouts; for tomatoes; for lettuce; for potatoes; for sweet potatoes in storage (Southern States only); for use in commercial greenhouses and nurseries; for beans (dry, lima, snap); for bat and rodent control; for emergency use for agriculture, health or quarantine purposes; and for onions and garlic; and for lice control. There has been considerable controversy as to what uses were at issue during the hearing. Admission No. 2 sets forth those uses which the Department of Agriculture considers essential. Many of those uses have been canceled and no appeal was taken. The uses at issue in this hearing are only those noted in Admission 11.

The Pesticides Office and Environmental Defense Fund (EDF), in presenting their cases against continued registration for DDT, lean most heavily on evidence which, they contend, establishes: (1) That DDT and its metabolites are toxicants which persist in soil and the aquasphere; (2) that once unleased, DDT is an uncontrollable chemical which can be transported by leaching, erosion, runoff, and volatilization; (3) that DDT is not water soluble and collects in fat tissue; (4) that organisms tend to collect and concentrate DDT; (5) that these qualities result in accumulations of DDT in wildlife and humans; that once stored or consumed, DDT can be toxic to both animals and humans, and in the case of fish and wildlife inhibit regeneration of species; and (7) that the benefits accruing from DDT usage are marginal, given the availability of alternative insecticides and pest management programs, and also the fact that crops produced with DDT are in ample supply. The testimony and exhibits include numerous reports of expert scientists who have described observed effects of DDT in the environment and the laboratory.

Group Petitioners and the U.S. Department of Agriculture (USDA) seek to discredit the Agency's case by citing the record of safety DDT has compiled throughout the years, and point to the negative findings of epidemiological and human feeding studies carried out over the years on industrial workers and volunteers exposed to concentrated levels of DDT far in excess of that to which the average individual is exposed. Proponents of continued registration have also introduced expert testimony to the effect that DDT's chronic toxicity to man or animals has not been established by adequate proof. The registrants have attacked the assumption that laboratory data, as to effects of exaggerated doses of DDT, can provide a meaningful basis for extrapolating effects on man or the environment. In the alternative, Group Petitioners contend that whatever harm to the environment might be attributed to DDT, it results from misuse and overdosing that occurred in years past. Lastly, Group Petitioners and USDA have attempted to prove that DDT is effective and that its use is more desirable than the organophosphates which are more acutely toxic and costly than DDT.

On April 25, the Hearing Examiner issued an opinion with proposed findings, conclusions and orders recommending that all "essential" uses of DDT be retained and that cancellation be lifted.[11] The Examiner's report which has findings, conclusions, and an opinion, is attached below. The Examiner apparently accepted in his report the Agency's proof that DDT is a hazard to aquatic and terrestrial wildlife and substitutes exist. He found, as a "matter of fact," DDT can have adverse effects on beneficial animals; that it is transferred through the food chain; that DDT is fat soluble. He concluded, however, as a "matter of law," that DDT is neither a carcinogen nor teratogen, that the particular uses at issue do not adversely affect wildlife, that DDT use has rapidly declined. (Examiner's Rept. p. 93.)

The Pesticides Office of this Agency and intervenor Environmental Defense Fund (EDF) filed exceptions to the Examiner's report,[12] challenging his application of the burden of proof to this case, his findings of fact, conclusions of law, and numerous evidentiary rulings. Exception was also taken to the Examiner's application of the so-called "risk and benefit" standard of FIFRA.

On May 2, 1972, the Judicial Officer propounded by order, at my direction, a series of questions for briefing and discussion at oral argument, and oral argument was held on May 16. That argument was transcribed and is part of this record. Group Petitioners, USDA, Eli Lilly, and H. P. Cannon & Sons have also responded to the briefs on exceptions.

II.—A. *Applicable law*. The basic FIFRA scheme has been outlined in court opinions and Agency decisions (see EDF v. EPA, D.C. Cir. Slip. Op. 71-1365, ______ F. 2d ______, May 5, 1972 (opinion of Judge Leventhal); Stearns Elec. Paste Co. v. EPA, 7th Cir. Slip Op. No. 71-1112, ______ F. 2d ______, May 11, 1972; Continental Chemiste Co. v. EPA, 7th Cir. Slip Op. No. 71-1828, ______ F. 2d ______, May 11, 1972; EDF v. Ruckelshaus (opinion of Judge Bazelon), supra; Statement of Reasons Concerning the Registration of Products Containing DDT, 2,4,5-T, and Aldrin/Dieldrin, March 18, 1972; In re Hari-Kari Lindane Pellets, et al., I.F.&R. No. 6 (1971)). While there is no need to trace in detail once again the statutory scheme, a brief summary provides a useful prism for filtering the evidence.

1. *FIFRA*. The Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. section 135 (1972), establishes a strict standard for the registration of pesticides. Any "economic poison" which cannot be used without injury to "man or other vertebrate animals, vegetation, and useful invertebrate animals" is "misbranded,"[13] and is therefore subject to cancellation.[14]

While the language of the statute, taken literally, requires only a finding of injury to nontarget species, the inquiry cannot, however, end with a simplistic application of this plain statutory language. Both judicial and administrative precedent recognize that Congress intended the application of a balancing test, that would measure the risks of using a particular chemical against its benefits.[15] If a product is "misbranded" within the meaning of the Act, i.e., if it bears a label for use that does not meet the criteria of section 2, it may no longer be shipped in interstate commerce and stocks in hand in the original package may be seized. 7 U.S.C. section 135(g) (1972).

2. *Risks and benefits*. It follows from the statutory scheme and this Agency's decisions that evidence of each alleged risk must be reviewed and a conclusion reached as to whether or not, and in what degree, such risk is incident to the directed use of a particular product. The task, however, is complicated in the case of a "persistent" pesticide by its possible chronic effects. The degree of persistence, extent of overall usage and mobility all bear on the amplitude or indeed the existence of the risk curve.[16] I believe, however, it is useful to isolate the alleged risks and evaluate each on the assumption that they are unaffected by overall levels of use, and defer to Part IV the discussion of the significance of the relationship between risk and overall use.

III.—A. *Analysis of evidence.—1. Risks—a. Health effects and environmental properties.* There is no dispute on this record that DDT is a nonspecific chemical that kills both target and nontarget species in the immediate area of application. Few chemicals, however, are so selective that they can be used without causing some injury to "nontarget" species. We must therefore proceed to the evidence bearing on other "risks" and the "benefits" from using DDT.

I am convinced by a preponderance of the evidence that, once dispersed, DDT is an uncontrollable, durable chemical that persists in the aquatic and terrestrial environments. Given its insolubility in water and its propensity to be stored in tissues, it collects in the food chain and is passed up to higher forms of aquatic and terrestrial life. There is ample evidence to show that under certain conditions DDT or its metabolites can persist in soil for many years,[17] that it will volatilize or move along with eroding soil.[18] While the degree of transportability is unknown, evidence of record shows that it is occasionally found in remote areas or in ocean species, such as whales, far from any known area of application.

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[11] There is some confusion as to what the term "essential" means. By Admission No. 2 the parties stipulated that certain uses were "essential" in the view of USDA. No stipulation exists that these uses are, in fact, essential in that no alternatives exist or that a shortage of a crop would result without DDT.

[12] Exceptions have also been received in Docket 106, In Re Wallerstein. Stark Bros. Nurseries held a registration for use of DDT on nursery plants. The Examiner recommended cancellation on the grounds that this was not an "essential" use according to USDA.

[13] Secs. 2(z)(2) (c), (d), and (g), respectively provide:

"The term 'misbranded' shall apply—

(a) To any economic poison—

* * * * *

(c) If the labeling accompanying it does not contain directions for use which are necessary and if complied with adequate for the protection of the public;

(d) If the label does not contain a warning or caution statement which may be necessary and if complied with adequate to prevent injury to living man and other vertebrate animals, vegetation, and useful invertebrate animals;

* * * * *

(g) If in the case of an insecticide, nematocide, fungicide, or herbicide when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison;

* * * * *

[14] Sec. 4 permits the Administrator to cancel a registration "if it appears that 'the article and its labeling * * *' do not comply with [the Act]." Since the Act prohibits distribution of a "misbranded" pesticide, sec. 3 (a)(5), the registration for a "misbranded" product may be canceled.

[15] See EDF v. EPA (opinion of Judge Leventhal), supra; EDF v. Ruckelshaus (opinion of Judge Bazelon), supra, DDT Statement of Reasons, supra; see also Statement of Reasons Underlying Suspension and Cancellation of Products Containing Mercury, 37 F.R. 6419 (Mar. 29, 1972).

[16] Other factors bearing on risk may include the geographical location of application, see, e.g., Statement of Reasons Underlying Registrations for Strychnine, 1080, and Sodium Cyanide, 37 F.R. 5718 (1972), although this may not be as significant where the chemical is highly volatile as is the case with DDT. See also Statement of Reasons Underlying the Cancellation of Mirex, Determination and Order of the Administrator at 7 (37 F.R. 10987, June 1, 1972).

[17] Method of application and type of soil and climate can affect persistence in soil and likewise runoff into aquatic areas.

[18] Registrants have made much of the fact that aquatic contamination and the spread of DDT have resulted from drift during aerial application. While the Examiner's report dwells at some length on improved methods of application, it recognizes runoff as a significant source of aquatic contamination, even with improved aerial spraying techniques.

Persistence and biomagnification in the food chain are, of themselves, a cause for concern, given the unknown and possibly forever undeterminable long-range effects of DDT in man, and the environment.[19] Laboratory tests have, however, produced tumorigenic effects on mice when DDT was fed to them at high levels.[20] Most of the cancer research experts who testified at this hearing indicated that it was their opinion that the tumorigenic results of tests thus far conducted are an indicator of carcinogenity and that DDT should be considered a potential carcinogen.[21]

Group Petitioners argue that the testimony is in conflict and fasten on to the testimony of the Surgeon General that of Drs. Loomis and Butler. The Surgeon General's statement was, however, cautious and, by no means, carries the burden that the Group Petitioners seek to place on it. In very general terms the Surgeon General stated: "We have no information on which to indict DDT either as a tumorigen or as a carcinogen for man and on the basis now available, I cannot conclude DDT represents an imminent health hazard." (Tr. 1350.) This testimony, however, does not bear on the long-term effects of DDT, nor did the Surgeon General express a view on what uses, apart from health uses, would justify continued use of DDT. Indeed, the entire thrust of the Surgeon General's testimony was only that use for immediate health needs outweighs the possible long-range effects of DDT on human health. Group Petitioners' other witnesses, Drs. Loomis and Butler, while men of stature in their fields—toxicology and pathology—and knowledgeable about cancer treatment and diagnosis, are not specialists in cancer research as is Dr. Saffiotti. Indeed, Dr. Butler disclaimed such expertise.

Group Petitioners also take refuge under a brond canopy of data—human feeding studies and epidemiological studies—and support it with the increasingly familiar argument that exposure to any substance in sufficient quantities may cause cancer.

None of the feeding studies carried out with DDT have been designed adequately to detect carcinogenicity, and given the latency period of cancer, these studies would have to be carried out for a much longer period. Statistical population samples for epidemiological studies are also virtually impossible given the latency period for cancer and the long-term exposure of the general population. Since there is no sharp distinction between population groups exposed to low doses and higher doses of DDT, adequate control groups cannot be established. The "everything is cancerous argument" fails because it ignores the fact that not all chemicals fed to animals in equally concentrated doses have produced the same tumorigenic results.

b. *Environmental effects.* The case against DDT involves more, however, than a long-range hazard to man's health. The evidence presented by the Agency's Pesticides Office and the intervenors, EDF, compellingly demonstrates the adverse impact of DDT on fish and birdlife. Several witnesses testified to first-hand observed effects of DDT on fish and birdlife, reporting lethal or sub-acute effects on aquatic and avian life exposed in DDT-treated areas. Laboratory evidence is also impressively abundant to show the acute and chronic effects of DDT on avian animal species and suggest that DDT impairs their reproductive capabilities.[22]

The petitioner-registrants' assertion that there is no evidence of declining aquatic or avian populations, even if actually true, is an attempt at confession and avoidance. It does not refute the basic proposition that DDT causes damage to wildlife species. Group petitioners' argument that DDT is only one toxic substance in a polluted environment, and thus, whatever its laboratory effects, it cannot be shown to be the causative agent of damage in nature, does not redeem DDT, but only underscores the magnitude of effort that will be necessary for cleaning up the environment. Were we forced to isolate in nature, rather than in the laboratory, the effects of various toxic substances, it would be difficult if not impossible to make a judgment as to the chronic effects of any chemical. As our DDT statement of March 1971 has noted: "Development of adequate testing protocols and facilities is a priority undertaking. But in the short term, extrapolation from small-scale laboratory analyses must err on the side of safety." See DDT Statement of Reasons, at 11.

Finally, I am persuaded that a preponderance of the evidence shows that DDE causes thinning of eggshells in certain bird species. The evidence presented included both laboratory data and observational data. Thus, results of feeding experiments were introduced to show that birds in the laboratory, when fed DDT, produced abnormally thin eggshells. In addition, researchers have also correlated thinning of shells by comparing the thickness of eggs found in nature with that of eggs taken from museums. The museum eggs show little thinning, whereas eggs taken from the wild after DDT use had become extensive reveal reduced thickness.

Group Petitioners and USDA argue that the laboratory feeding studies, conducted with exaggerated doses of DDE and under stress conditions, provide no basis for extrapolating to nature. They suggest that the study results are contradictory and place particular emphasis on documents which were not part of the original record and the inconsistencies in Dr. Heath's testimony as brought out during cross-examination. Group Petitioners also contend that the observed phenomenon of eggshell thinning and DDE residue data are tied by a statistical thread too slender to connect the two in any meaningful way.

Viewing the evidence as a total picture, a preponderance supports the conclusion that DDE does cause eggshell thinning. Whether or not the laboratory data above would sustain this conclusion is beside the point. For here there is laboratory data and observational data, and in addition, a scientific hypothesis, which might explain the phenomenon.[23]

B. *Benefits*—1. *Cotton.* I am convinced by the evidence that continued use of DDT is not necessary to insure an adequate supply of cotton at a reasonable cost. Only 38 percent of cotton-producing acreage is treated with DDT, although the approximately 10,277,228 pounds used in cotton production is a substantial volume of DDT and accounts for most of its use. The record contains testimony by witnesses called by registrants and USDA attesting to the efficacy of organophosphate chemicals as substitutes for DDT and, long-range, the viability of pest management methods, such as the diapause program. At present most areas that use DDT combine it with an organophosphate and toxaphene in a 4-2-1 mixture (4 lbs. toxaphene, 2 DDT, 1 methyl parathion). Some areas, however, according to the testimony, which normally use DDT occasionally apply concentrated methyl parathion in a 4-pound mixture.

There is evidence that organophosphates would not raise costs to the farmer and might, indeed, be cheaper. Any suggestion that the organophosphates are not economically viable cannot be maintained in face of the undisputed evidence that cotton continues to be tenable crop in Arkansas and Texas where DDT use has declined.[24] There is

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[19] It is particularly difficult to anticipate the long-range effects of exposure to a low dose of a chemical. It may take many years before adverse effects would take place. Diseases like cancer have an extended latency period. Mutagenic effects will be apparent only in future generations. Lastly, it may be impossible to relate observed pathology in man to a particular chemical because of the inability to isolate control groups which are not exposed in the same degree as the rest of the population.

[20] Tumorigenic effects have been noted in a number of laboratory experiments. The most positive results were developed by the Bionetics Study and the Lyons and Milan tests. The Bionetics Study of the National Cancer Institute fed 120 compounds to two strains of mice. DDT was one of 11 compounds to produce an elevated incidence of tumors. The Lyons and Milan Studies of the International Agency for Research of the World Health Organization is a multigenerational study (still in progress) of 6,000 mice of in- and out-bred strains. Increased hepatomas were noted in male and female mice fed DDT at 250 p.p.m. Matastasis to the lungs or kidneys has been recorded in five instances.

[21] Witnesses testifying to the positive correlation between tumorigens and carcinogens were Dr. Umberto Saffiotti, Associate Scientific Director for Carcinogenesis, Etiology Area, National Cancer Institute; Dr. Marvin Schneiderman, Associate Chief, Biometry Branch and Associated Director for Demography, National Cancer Institute; Dr. Samuel Epstein, Senior Research Associate in Pathology, Children's Cancer Research Foundation, Inc., Boston.

[22] See the testimony of Drs. Tarzwell, Nicholson, Philip Butler, Duke, Burdick, Dimond, Risebrough, Hickey, and Cade.

While the Examiner erroneously excluded testimony as to economic losses caused by DDT's contamination of the aquatic environment—losses to commercial fishermen caused by inability to market contaminated fish—this risk is significant, even if it could not be economically quantified. Not all risks can be translated into dollars and cents, nor can all benefits be assessed in cash terms.

[23] The chief witness introduced to rebut Drs. Risebrough, Hickey, and Cade was a graduate student with limited training in statistical analysis. In view of the credentials of EDF's witnesses—Dr. Hickey, Professor of Wildlife Zoology at College of Agriculture, University of Wisconsin; Dr. Risebrough, Associate Ecologist, University of California at Berkeley; and Dr. Cade, Professor of Zoology at Cornell and Research Director of Cornell Ornithology Laboratory—I cannot credit this attempt at rebuttal.

The Hearing Examiner apparently resolved the conflict in the evidence by concluding that "there was no evidence that DDT was the only factor in a decline of bird populations * * *" and that no evidence "focused its direct thrust on damage to birds by the user of DDT that are permitted under the registrations in question." Examiner's Report, 70-71. In view of DDT's persistence and mobility, evidence as to the causal effect of these uses was not required.

At argument and by motion Group Petitioners have offered additional evidence, some of which bears on the issue of eggshell thinning. I have granted that motion and considered all that data.

[24] The parties have referred neither in briefs nor argument to testimony or exhibits describing in detail the economics of cotton production or substitutes. There is general testimony that cotton producers receive a per bushel subsidy and that this

(Footnote 24 continued on next page)

also testimony in the record to the effect that methyl parathion costs less per application than the DDT-toxaphene formula. Nor are the testimony and exhibits that show cotton insects develop resistance to organophosphate chemicals to the point. The very same exhibits make clear that DDT is also subject to resistance.[illegible]

Group Petitioners and USDA, while not disputing the lesser persistence of organophosphates, have stressed their demonstrated acute toxicity. While they are toxic to beneficial soil insects and non-target species, particularly birds alighting on treated fields, these organophosphates break down more readily than DDT. They apparently are not transported in their toxic state to remote areas, unlike DDT which has been found far from treated areas, and consequently do not pose the same magnitude of risk to the aquasphere. Both testimony and exhibits also demonstrate that organophosphates are less acutely toxic to aquatic life, although different compounds have different toxicities. The effect of organophosphates on non-target terrestrial life can, unlike the effects of DDT, also be minimized by prudent use. Application in known nesting areas for rare or extinct birds can be avoided.

2. *Other crop and produce uses.* The testimony of record, while sparse, shows that registered alternatives, primarily organophosphates, exist for all other crop and ornamental uses of DDT, except for storage use on sweet potatoes to control weevils, on heavy corn borer infestations of green peppers, and perhaps onions.[illegible]

3. *Noncrop uses.* In addition to the registrations for use on crops and in nurseries, several registrations for noncrop uses are also in issue. Admission 11 lists "public health pests—bats and rodents," "Agricultural, Health and Quarantine Treatments in Emergencies as Recommended by and Under Direction of State-Federal Officials" and "fabric treatment" by the military.

The record is not, unfortunately, well developed as to the scope or method of application for these uses nor as to the overall volume applied for these purposes. While use for bat and mice control is characterized in Admission 11 as a "public health use," application for these purposes is not supervised by public health officials. The briefs suggest that use for control of bats and mice is a proprietary use by the military, even though a private pest control operator testified that use for bats was considered essential by private operators.[illegible] With respect to "Agricultural and Quarantine" uses it is difficult to determine to what extent applications are for health purposes or for nuisance prevention.

With respect to all of these uses, both for public health programs and proprietary use, alternatives do exist. The Public Health Service testified that DDT is no longer the chemical of choice for controlling disease vectors. As for mice, warfarin is used effectively, and fumigation and nonchemical means are available for use on bats. Colonel Fowler testified that the military has not used DDT in this country for 2 years for mothproofing purposes and stated that he was aware of alternatives.

C. *Weight to be accorded the examiner's opinion.* In reaching the factual conclusions set forth in the preceding sections, I have been mindful of Group Petitioners' argument, stressed in their briefs and at oral argument, that the Hearing Examiner's findings deserve particular deference in view of his opportunity to resolve contradictions in testimony based on demeanor evidence.

Nowhere does the Examiner state that his conclusions were based on credibility choices.[illegible] Whatever extra weight, then, that might be due findings based expressly on a credibility judgment is not appropriate in the case before me. See, e.g., NLRB v. Dinion Coil Co., 201 F. 2d 484 (2d Cir. 1952) where the Examiner's report set forth his assessment of the witnesses' credibility.[illegible]

IV. The application of the risk-benefit test to the facts of record is, by no means, simple. We have noted in our statement of March 18, 1971, that the variables are numerous. It should also be borne in mind that the variables are not static in point of time. As buildup of a chemical occurs or is detected in the environment, risk increases. Indeed, it may be that the same tendency of a chemical to persist or build up in the food chain is present but not known about substitute chemicals. It may also be that circumspect application of a chemical in limited quantities for those uses most necessary changes the benefit-risk coefficients so as to tilt the scales differently than when we weigh aggregate use for all purposes against aggregate benefits. See generally EDF v. EPA (opinion of Judge Leventhal), supra.

A. *Burden of proof.* The crux of a cancellation proceeding is the safety of the product when used as directed or in accordance with "commonly recognized practice." *Stearns Phosphorus Paste Co. v. EPA*, supra. This, simply stated, means that this Agency has the burden of going forward to establish those risks which it believes to require cancellation.[illegible] In addition, an affirmative aspect of the Agency's case should be the availability of preferable substitute means of controlling the pests that are controlled by the canceled chemical where the Agency is relying on this fact to establish that risks outweigh benefits.[illegible] Evidence showing the availability of a registered chemical or other means of control which this Agency's Pesticides Office is prepared to recommend as a substitute at that point in time, coupled with the Agency's proof on risk, makes out an affirmative case.[illegible]

The burden of rebuttal then falls on registrants or users. They may either seek to negate the proof on risks either by rebutting the basic scientific data or by showing that a particular use is so limited as not to en-

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[illegible]—Continued.
subsidy is the difference between profit and break-even. It is not clear whether or not break-even includes a return to the farm owner in terms of salary or return on his investment. While some evidence suggests that organophosphates are more costly, because of higher price and the need for repeated applications in concentrated quantities, there is little to suggest that the possible increased variable cost from use of organophosphates would be a disincentive to producers. Indeed, with subsidies it is not clear what rate of return a cotton producer receives for invested capital. There was a reference made to an unidentified study showing that the cost of using substitutes would involve $15 million. This figure alone has no meaning. While later testimony suggests that elimination of DDT would increase variable costs per acre by 5 percent, this, too, is of limited significance since the record does not relate it to the support program and the study looked at only a limited area.

[illegible] I cannot accept the suggestion that we should continue to use DDT until it is good to the very last drop. Whatever the long-term efficacy of the organophosphates the fact remains that they generally work. While the fact of insect resistance is important and underscores the need for retaining a variety of chemicals or methods to manage the same pest problem, this fact does not justify an avoidable use of a harmful chemical.

[illegible] Toxaphene and diazinon are registered for control of cutworms but it is not clear from the record as to whether or not these chemicals are registered or effective to control cutworm infestations on onions. While none of the parties have pointed to helpful evidence in connection with use for controlling cutworms on onions and weevils on stored sweet potatoes, I have taken judicial notice of the nonexistence of registered alternatives.

[illegible] The only evidence as to the amount of DDT used for these purposes was given by Col. Fowler, who said the total used by the military for bat and mouse control is approximately 800–900 pounds.

[illegible] During oral argument counsel admitted that the Examiner's report did not purport to make findings based on credibility of witnesses, nor could he point to findings which might be explained in light of a credibility contest. (Transcript of Argument, p. 56–58.) The basic questions of fact in this case, the hazard to man and the environment, were cast and resolved by the Examiner as "conclusions of law."

[illegible] The precedents, moreover, make clear that the Agency is free to make its own findings and that the Examiner's findings and report only comprise part of the record which a court will then evaluate. FCC v. Allentown Broadcasting Corp., 349 U.S. 358 (1955); Universal Camera Corp. v. NLRB, 340 U.S. 474 (1951). Even where an Examiner's findings are based on credibility, the Agency may reach a contrary conclusion. See FCC v. Allentown Broadcasting Corp., supra.

[illegible] The legislative history of FIFRA, judicial decisions and Agency pronouncements all state that the "burden of proof" remains on the registrant to demonstrate that his product satisfies the requirements for registration under the Act. See S. Rept. 573 at 5 (88th Cong., first sess., 1963); H. Rept. 1125 at 4 (88th Cong., first sess., 1963); EDF v. EPA, supra; EDF v. Ruckelshaus, supra; Statement of Reasons, Mar. 18, 1971. There has, unfortunately, been a great deal of misunderstanding concerning these statements. Simply stated, the burden of proof referred to by the legislative history is the burden of persuasion which requires a party to establish the existence of primary facts. It should not be confused with the burden of going forward which is generally a rule to establish the order for the presentation of evidence. The burden of going forward may, however, have substantive consequences. Where a party which has the burden of going forward fails to satisfy that burden, the facts will be decided against him, even though the other party may have been responsible for the burden of persuasion.

While in most legal proceedings the party which has the burden of going forward bears the burden of persuasion, this is not necessarily the case. On some issues, like contributory negligence in some jurisdictions, it may be that once one party has introduced evidence to put the issue in the case, the other party bears the burden of persuasion on that point. In a FIFRA cancellation hearing the proponent of cancellation bears the burden of going forward, but does not bear the burden of persuasion.

[illegible] While a mere showing of a high degree of risk would make out a prima facie case for cancellation, where the Agency is relying on the existence of an alternative rather than simply a showing of risk, it should, as here, present its own witnesses.

[illegible] This hearing was conducted under rules which have since been amended. (See 37 F.R. 9476 (May 11, 1972)). Under the Agency's former rules registrants proceeded first at the hearing. This order of presentation, which is now changed, was not prejudicial in this case. The Agency more than discharged its burden to put on a prima facie case. Registrants had an ample opportunity for rebuttal. At worst this inverted presentation unnecessarily protracted the hearing.

gender the risks from widespread use of the chemical. They can also seek to establish aggregate benefits. Where, as here, the existence of alternatives bears on the benefit of the chemical under review they may choose to show nonviability of alternatives, either for general substitution or in a particular geographical region.[illegible] They may also seek to show the nondesirability (or risks) of the alternative if they disagree with the staff judgment of this Agency.

B. *Application of risk-benefit to crop uses of DDT.* The Agency and EDF have established that DDT is toxic to nontarget insects and animals, persistent, mobile, and transferable and that it builds up in the food chain. No label directions for use can completely prevent these hazards. In short, they have established at the very least the risk of the unknown. That risk is compounded where, as is the case with DDT, man and animals tend to accumulate and store the chemical.[illegible] These facts alone constitute risks that are unjustified where apparently safer alternatives exist to achieve the same benefit. Where, however, there is a demonstrated laboratory relationship between the chemical and toxic effects in man or animals, this risk is, generally speaking, rendered even more unacceptable, if alternatives exist. In the case before us the risk to human health from using DDT cannot be discounted. While these risks might be acceptable were we forced to use DDT, they are not so trivial that we can be indifferent to assuming them unnecessarily.

The evidence of record showing storage in man and magnification in the food chain is a warning to the prudent that man may be exposing himself to a substance that may ultimately have a serious effect on his health.

As Judge Leventhal recently pointed out, cancer is a "sensitive and fright-laden" matter and noted earlier in his opinion that carcinogenic effects are "generally cumulative and irreversible when discovered." EDF v. EPA, Slip Op. at 12 and 16. The possibility that DDT is a carcinogen is at present remote and unquantifiable; but if it is not a siren to panic, it is a semaphore which suggests that an identifiable public benefit is required to justify continued use of DDT. Where one chemical tests tumorigenic in a laboratory and one does not, and both accomplish the same task, the latter is to be preferred, absent some extenuating circumstances.

The risks to the environment from continued use of DDT are more clearly established. There is no doubt that DDT runoff can cause contamination of waters and given its propensity to volatilize and disperse during application, there is no assurance that curtailed usage on the order of 12 million pounds per year will not continue to affect widespread areas beyond the location of application. The Agency staff established, as well, the existence of acceptable substitutes for all crop uses of DDT except on onions and sweet potatoes in storage and green peppers.

Registrants attempted but failed to surmount the evidence of established risks and the existence of substitutes by arguing that the buildup of DDT in the environment and its migration to remote areas has resulted from past uses and misuse. There is, however, no persuasive evidence of record to show that the aggregate volume of use of DDT for all uses in question, given the method of application, will not result in continuing dispersal and buildup in the environment and thus add to or maintain the stress on the environment resulting from past use. The Department of Agriculture has, for its part, emphasized DDT's low acute toxicity in comparison to that of alternative chemicals and thus tried to make the risk and benefit equation balance out favorably for the continued use of DDT. While the acute toxicity of methyl parathion must, in the short run, be taken into account, see infra, it does not justify continued use of DDT on a long-term basis. Where a chemical can be safely used if label directions are followed, a producer cannot avoid the risk of his own negligence by exposing third parties and the environment to a long-term hazard.

Accordingly, all crop uses of DDT are hereby canceled except for application to onions for control of cutworm, weevils on stored sweet potatoes, and sweet peppers. Shipments of DDT labeled for those uses may continue on terms set forth in Part V–A. We defer to Part V–B, infra, consideration of the proper timing of cancellation of other uses in light of the short-run dangers of switching to the use of organophosphates without providing training.[illegible]

C. *Application of risk-benefit to noncrop uses.* There remains the question of the disposition on the registered health and Government uses and other noncrop uses of DDT. It should be emphasized that these hearings have never involved the use of DDT by other nations in their health control programs. As we said in our DDT statement of March 1971, "this Agency will not presume to regulate the felt necessities of other countries." Statement, at 8. Indeed, the FIFRA does not apply to exports. Section 7, 7 U.S.C. section 135 (1972).

Given the alternatives for mothproofing and control of bats and mice—proprietary governmental uses of DDT—I am persuaded that the benefits are even more de minimis than the risks. On the other hand, public health and quarantine programs fall into a wholly separate category. See EDF v. Ruckelshaus, 439 F. 2d at 594; DDT Statement of Reasons at 11.

While alternatives also exist for use in public health quarantine programs and, in most instances, DDT is no longer the premium chemical, I believe that it would be unwise to restrict knowledgeable public officials to the choice of one or two chemicals. Like a physician, the public official must have an ample arsenal for the combat of disease and infestation.

I cannot, however, be indifferent to the fact that the record suggests that "health and quarantine" uses have, in the past, apparently included proprietary uses by government. Nor can I be complacent about nonsupervised use for these purposes by private citizens. I am, accordingly, requiring a label which will restrain indiscriminate use of DDT for a wide variety of purposes under the rubric of official use. That label language is set forth in the order accompanying this opinion, and is designed to restrict shipment of DDT only to U.S. Government officials and State health departments who will be knowledgeable as to the most effective means for control and mindful of the risks of using DDT. Thus, on an application-by-application basis for necessary health and quarantine purposes, the benefits will be maximized and outweigh the risks.[illegible] Cf. 42 U.S.C. section 4332 (1971) which requires an environmental impact statement on ongoing official programs.

V. I turn now to the disposition of these dockets in light of the foregoing principles. At the outset it should be noted that recent judicial decisions have urged this Agency to use its "flexibility, in both final decisions and suspension orders, to differentiate between uses of the product." (See EDF v. EPA (opinion of Judge Leventhal), supra, at 20), and reminded us that creative adaptability is the keystone of a workable regulatory process. Cf. SEC v. National Securities, Inc., 393 U.S. 453, 463 (1969). EDF v. EPA, while discussing suspension, serves as a beacon in this regard, suggesting that registration be continued selectively, taking into account "restrictions on kinds and extent of use." Id. at 23. Bearing these principles in mind, I turn first to the form and shape our orders should take.

A. *Disposition as to onions, stored sweet potatoes, and sweet peppers.* There is evidence that DDT is the only useful chemical for controlling heavy corn borer infestations which attack green peppers in the Del Marva Peninsula. The record shows that about 13,000 pounds of DDT are used regularly as a ground application for prophylactic purposes. Sevin, guthion, and phosphamidon can, however, be used at less than 30 percent infestation. Del Marva produces less than 5 percent of the nation's sweet peppers and other crops can be profitably produced. The Agency staff has conceded in its April 15 brief in support of proposed findings, conclusions, and order that this use of DDT "comes closest—of all the uses in issue—to being necessary in the sense that no real alternative insect control method exists under certain conditions." (Brief, at 93.)

The evidence concerning use of DDT to control cutworms is less clear cut. Apparently cutworm infestations in the Northwest are sporadic and localized. While it would appear that other chemicals could be used to control cutworm infestations on

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[illegible] Where there is a generally viable substitute, which will insure an adequate crop supply, the nonviability of the alternative in a particular area will bear on the advisability of a transition period. See part IV, infra.

[illegible] In enacting the present law one of the greatest concerns expressed to Congress was the risk of the unknown. See statement of Congressman Dingell, Hearings before the Subcommittee on Departmental Oversight and Consumer Relations of the House Committee on Agriculture, at 39 (88th Cong., first sess., 1963).

[illegible] Registrants adduced considerable testimony on the effects of organophosphates on nontarget species. Sevin, it appears, is highly toxic to bees and most witnesses agreed that the organophosphates were toxic to nontarget animals, usually birds and insect life, present when a field is sprayed. The present evidence demonstrates, however, that these organophosphate compounds are less "persistent," and thus do not leach or erode into waters or collect in the human food chain. While it may be that in time the familiar phrase "familiarity breeds contempt" will apply, as we learn more about these compounds, they appear not to present a long-range hazard to man or aquatic areas. Where registrants have scored, is by demonstrating the acute toxicity of methyl parathion which is the primary alternative chemical for many of the crop uses in question. That fact does not, however, alter the long-term balance between the risks and benefits, in view of the nonpersistence of the organophosphates.

[illegible] The use of DDT in Topocide, a prescription drug, is regulated by both the Food and Drug Administration and this Agency. The alternative, Kwell, is a lindane product. I am, however, taking judicial notice of the fact that lindane registrations are presently under review by this Agency's Pesticides Office and several uses of lindane have, in the past, been the subject of cancellation proceedings. See In Re Hart Karl Lindane, supra. I am not prepared to judge on this record whether or not the risk to the environment and the public at large from DDT shampoo is greater than from lindane shampoo. As for the direct effects on the user of the drug, this matter is for FDA and the prescribing physician.

onions as with peanuts, none are apparently registered. No party has cited evidence of record showing what percent of the onion-producing acreage would be affected by a cancellation of DDT.

The evidence with respect to use of DDT as a "dip" to protect stored sweet potatoes against weevil infestation is even spottier. Neither counsel for the parties nor our research has pointed us to evidence of record showing the precise volume of DDT use for this purpose, its likely effect on the environment, or the degree of loss that might be sustained by producers.

While it would be far easier simply to cancel or not cancel the registrations for these uses, I believe that environmental problems should be pared with a scalpel, not a hacksaw. While EDF and my own staff urge cancellation, on the ground that producers can easily shift to producing different crops, there is no evidence as to how long such transition might require. Moreover, it may be that continued use of a limited volume of DDT in these few areas, taken in conjunction with aggregate volume of use for other purposes, like health, present no risk to the environment. Obviously much of the stress on the "global" environment is reduced by curtailing overall volume of usage and we must then estimate the impact of use, both on the environment as a whole, and the local surroundings. Lastly, it may well be relevant to examine the impact on overall supply of a commodity. Even though peppers, onions, and sweet potatoes may not be food "staples," it may be that the other acreage is not suited for producing these crops. In that event, it will be necessary to determine whether or not supplies will satisfy demand, and whether or not a transition period should be fixed to permit a market adjustment.[illegible]

It follows that additional evidence is required to determine the answers to these questions. In the interim the cancellation orders will remain in effect, subject to registrants or users petitioning to present additional evidence. In that event, a stay order will issue pending the determination on remand. If these users or registrants can demonstrate that a produce shortage will result and their particular use of DDT, taken with other uses, does not create undue stress on the general or local environment, particularly the aquasphere, cancellation should be lifted. If no produce shortage will result because other acreage is suitable for these crops, it shall still be open to demonstrate that a transitional period is required for switching to new crops. If the interim use of DDT does not constitute an environmental risk, final orders of cancellation for these uses will be deferred until the transition can be accomplished, provided assurances are received at the hearing that formulators and users will not permit bootlegging.

B. *The switch to methyl parathion*. The need for a transition period arises also in connection with those uses that are being canceled based on the existence of methyl parathion.

The record before me leaves no doubt that the chief substitute for most uses of DDT, methyl parathion, is a highly toxic chemical and, if misused, is dangerous to applicators.[illegible] This was the virtually unanimous opinion of all the witnesses. The introduction into use of organophosphates has, in the past, caused deaths among users who are untrained in their application and the testimony and exhibits of record point to the unhappy experience of several years ago where four deaths occurred at the time ethyl parathion began to be used on tobacco crops. Other testimony noted the increase in nonfatal accidents and attributed almost one-half reported pesticide poisonings to the organophosphate group. A survey conducted after the organophosphates began to replace chlorinated hydrocarbons in Texas suggests a significantly increased incidence of poisonings.

That the skilled and trained user may apply organophosphates with complete safety is of comfort only if there is an orderly transition from DDT to methyl parathion so as to train workers now untutored in the ways of proper use.

I am accordingly making this order effective as of December 31, 1972, insofar as the cancellations of any particular use is predicated on the availability of methyl parathion as a substitute. In the months that follow the Department of Agriculture and State extension services and representatives of EPA will have time to begin educating those workers who will have to use methyl parathion in future growing seasons. Such a program can also introduce farmers to the less acutely toxic organophosphates, like carbaryl, which may be satisfactory for many uses.

VI. Far from being inconsistent with the general congressional mandate of FIFRA, a period of adjustment to train users of methyl parathion or permit a needed transition where no substitutes exist is a logical outgrowth of a sensible application of risk-benefit analysis. While the legislative history does not address the specific problem before me—the timing of cancellation orders—the hearings that preceded the enactment of FIFRA indicate that congressional concern for safety of the farmer-user of pesticides was no less than Congress' solicitude for the environment. While Congress ultimately struck a balance that generally places the risk of negligence on the applicator, see Stearns v. EPA, supra, it did so in light of assurances that farmers are for their own safety as well as that of the environment being trained in proper methods of application. See Hearings before the Subcommittee on Departmental oversight and Consumer Relations of the House Committee on Agriculture, supra, at 54, 63.[illegible]

The risk-benefit equation is a dynamic one. Timing is a variable in that equation. What may, in the long run, be necessary to protect the environment could be a short-term threat to human health. This is exactly the case before me now. The benefits of using organophosphates are a long-range benefit and the risks of DDT result from continued long-term use. In the very short run, however, the equation balances out very differently.[illegible] Likewise, the prospect of dislocation which might ensue were the use of DDT immediately halted where no alternative is used is a factor we must reckon with. The major environmental regulatory statutes, enacted and pending, provide "leadtime" for an adjustment to new requirements.[illegible]

While impatience is understandable in view of the past history of delay, we must not be lulled into the belief that longstanding problems can be corrected by overnight solutions. Today's decision provides a definitive answer to the status of DDT registrations and all concerned: to this Agency, farmers, manufacturers, the Department of Agriculture, and extension services; all must proceed with alacrity toward the implementation of this order.

FACTUAL FINDINGS

I. SCOPE OF CASE

A. PR Notices 71-1, 71-3, 71-5 canceled all registered uses of DDT and TDE.

B. Appeals have been received by 31 formulators who hold registrations for formulating DDT or TDE. These formulators appeared at this proceeding by a single counsel.

C. Wyco, Inc. and the Wallerstein Co. and Stark Bro's. Nurseries have also appeared by separate counsel.

D. The Plant Regulation Division of the Department of Agriculture was a party to this hearing as a registrant and the Department was an intervenor as to all uses.

E. Eli Lilly & Co. and H. P. Cannon & Sons were parties to this hearing.

F. National Agricultural Chemicals Association; Environmental Defense Fund; the Sierra Club; West Michigan Environmental Action Council; and National Audubon Society are intervenor parties.

G. The following canceled uses were appealed and at issue in this hearing:

Crop Uses

1. Cotton.
2. Beans (dry, lima, snap).
3. Sweet potatoes.
4. Peanuts.
5. Cabbage, cauliflower, and brussels sprouts.
6. Tomatoes.
7. Fresh market corn.
8. Sweet peppers and pimentoes.
9. Onions.
10. Garlic.
11. Commercial greenhouses.

[illegible] It is a recognized policy of common law nuisance and also of Federal environmental legislation to afford affected producers a transitional period for implementing new requirements.

[illegible] Not all of the possible substitutes for DDT are equally potent. For example, trichlorofon, monocrotophos, malathion, and carbaryl, among others, are available to control many cotton pests; carbaryl is an all-purpose chemical for most cotton pests. It is, however, abundantly clear that methyl parathion will be widely used.

[illegible] At least two courts have given express recognition to the similarity between the regulatory schemes in FIFRA and the Food, Drug, and Cosmetic Act. See Welford v. Ruckelshaus, 439 F. 2d 598 (D.C. Cir. 1971); Nor-Am v. Hardin, 435 F. 2d 1133 (7th Cir. 1970) (en banc). I believe that the trail Congress intended me to follow is marked by its directive in section 340 of the Food, Drug, and Cosmetic Act, 21 U.S.C. section 348(f)(3) (1971), which permits the Secretary to set an effective date for his orders. While similar language has not been expressly included in FIFRA, its omission can hardly be considered advertent in view of the legislative history. See S. Rept. No. 573 (88th Cong., first session 1963); H. Rept. No. 1125 (88th Cong., second session 1964). The purpose of the 1964 amendments was to eliminate registration under protest.

[illegible] I do not believe that the Seventh Circuit's decision in Stearns Phosphorous Paste Co. v. EPA, supra, precludes me from taking into account the short-term dangers that could result from increased use of methyl parathion by untrained users. Stearns holds that a product is not "misbranded" simply because it can be highly dangerous if the user is careless. This reasoning does not, however, compel me to ignore the tendency of human beings to be negligent where we are dealing with the implementation of an order that will increase use of a highly dangerous substance. Even negligence can be minimized by training.

[illegible] While the Examiner excluded from evidence a study of the DDT problem for this Agency undertaken by a Committee of the National Academy of Sciences, it is appropriate to note that Committee recommended a phase-out period for the same reasons outlined in this opinion. While I reach my conclusions without relying on that report's factual findings and recommendations, and base them on the record as compiled below, I believe the report was erroneously excluded from the record, particularly in view of the offer by counsel for the Agency to produce a committee member for cross-examination.

Noncrop Uses

1. Control of house mice and bats (military only).

2. Fabric treatment (military only).

3. Disease vectors.

4. Quarantine.

5. Control of body lice in prescription drugs.

II. CHEMICAL PROPERTIES OF DDT

A. Basic findings:

1. DDT can persist in soils for years and even decades.

2. DDT can persist in aquatic ecosystems.

3. Because of persistence, DDT is subject to transport from sites of application.

a. DDT can be transported by drift during aerial application.

b. DDT can vaporize from crops and soils.

c. DDT can be attached to eroding soil particles.

4. DDT is a contaminant of freshwaters, estuaries and the open ocean, and it is difficult or impossible to prevent DDT from reaching aquatic areas and topography nonadjacent and remote from the site of application.

B. Ultimate finding:

The above factors constitute a risk to the environment.

III. ACTIVITY IN FOOD CHAIN AND IMPACT ON ORGANISMS

A. Basic findings:

1. DDT is concentrated in organisms and transferred through food webs.

a. DDT can be concentrated in and transferred through terrestrial invertebrates, mammals, amphibians, reptiles, and birds.

b. DDT can be concentrated and transferred in freshwater and marine plankton, insects, molluscs, other invertebrates, and fish.

2. The accumulation in the food chain and crop residues results in human exposure.

3. Human beings store DDT.

B. Ultimate finding:

The above factors constitute an unknown, unquantifiable risk to man and lower organisms.

IV. TOXICOLOGICAL EFFECTS

A. Basic findings:

1. DDT affects phytoplankton species' composition and the natural balance in aquatic ecosystems.

2. DDT is lethal to many beneficial agricultural insects.

3. DDT can have lethal and sublethal effects on useful aquatic freshwater invertebrates, including arthopods and molluscs.

4. DDT is toxic to fish.

5. DDT can affect the reproductive success of fish.

6. DDT can have a variety of sublethal physiological and behavioral effects on fish.

7. Birds can mobilize lethal amounts of DDT residues.

8. DDT can cause thinning of bird eggshells and thus impair reproductive success.

9. DDT is a potential human carcinogen.

a. Experiments demonstrate that DDT causes tumors in laboratory animals.

b. There is some indication of metastasis of tumors attributed to exposure of animals to DDT in the laboratory.

c. Responsible scientists believe tumor induction in mice is a valid warning of possible carcinogenic properties.

d. There are no adequate negative experimental studies in other mammalian species.

e. There is no adequate human epidemiological data on the carcinogenicity of DDT, nor is it likely that it can be obtained.

f. Not all chemicals show the same tumorigenic properties in laboratory tests on animals.

B. Ultimate finding:

DDT presents a carcinogenic risk.

V. BENEFITS

A. Basic findings:

1. DDT is useful for the control of certain cotton insect pests.

2. Cotton pests are becoming resistant to DDT.

3. Methyl parathion and other organophosphate chemicals are effective for the control of cotton pests.

a. Methyl parathion and organophosphates are less toxic to aquatic life than DDT.

b. Methyl parathion and organophosphates appear to be less "persistent" and do not build up in the food chain.

c. Methyl parathion is acutely toxic by dermal, respiratory exposure and oral ingestion.

4. By using methyl parathion or other means of pest control cotton producers can generally produce satisfactory yields at acceptable cost.

5. DDT is considered useful to have in reserve for public health purposes in disease vector control.

6. DDT is considered useful as a mothproofing agent.

a. DDT is not presently used by the military for treatment of fabric.

b. Alternatives exist.

7. DDT is useful for public quarantine programs.

8. Quarantine programs are administered by public officials and are a nonproprietary use of DDT.

a. This is of little use in controlling the overall gypsy moth problem.

9. DDT is useful for controlling certain insects that attack the crops listed in finding number (I) G.

10. Adequate substitute chemicals, namely, methyl parathion and other organophosphates—for the most part—exist for controlling the diseases that attack the crops listed in finding number (I) G except:

a. Sweet potatoes;

b. Heavy infestations of corn borer attacking sweet peppers grown on the Delmarva Peninsula;

c. Onions attacked by cutworms.

11. DDT is effective for controlling body lice:

a. Kwell, a Lindane product, is a substitute.

b. Lindane registrations are being reviewed.

12. DDT is used for exterminating bats and mice by the military.

a. Fumigation and nonchemical methods can guard against bat infestation.

b. Warfarin is effective for exterminating house mice.

B. Ultimate findings:

1. The use of DDT is not necessary for the production of crops listed in finding (I)7 except that it may be necessary to produce those crops listed in finding V10 (a), (b), and (c).

2. Noncrop uses of DDT for mothproofing and to control bats and mice are proprietary uses for which DDT is not necessary.

VI. MATTERS RELATING TO METHYL PARATHION

A. Basic findings:

1. Many poisonings have been attributed to the use of methyl parathion.

2. Untrained users of methyl parathion are frequently not sufficiently careful in its use despite label directions.

3. Methyl parathion can be used safely.

4. Training programs are useful in averting the negligent use of methyl parathion.

5. Methyl parathion is a substitute for most crop uses of DDT.

B. Ultimate finding:

1. Methyl parathion is dangerous to users and presents a risk to them.

2. An opportunity to train users will minimize the risks and keep down the number of accidents.

VII. GENERAL FINDINGS

A. No directions for use of DDT, even if followed, can over the long run completely eliminate DDT's injury to man or other vertebrate animals.

B. No warning or caution for use of DDT, even if followed, can over the long run prevent injury to living man and other vertebrate animals and useful invertebrate animals.

C. The present total volume of use of DDT in this country for all purposes is an unacceptable risk to man and his environment.

D. The use of DDT in controlled situations in limited amounts may present less risk than usage in greater amounts, but still contaminates the environment.

E. The public health program and quarantine uses of DDT by officials, when deemed necessary, can be judged on an application-by-application basis by professionals.

F. A particular official use, in an isolated instance, may be important.

CONCLUSIONS OF LAW

1. DDT formulations when labeled with directions for use in the production of those crops named in finding (I) G and for use on bats, mice, and fabric are "misbranded," within the meaning of section 2(z)(2) (c), (d), and (e) of FIFRA, 7 U.S.C. section 135.

2. DDT when labeled with directions "for use by and distribution to only U.S. Public Health Service officials or for distribution by or on approval by the U.S. Public Health Service to other health service officials for control of vector diseases, for use by and distribution to the Public Health Service, USDA, and military for quarantine use; for use in prescription drugs to be dispensed only on authorization by a certified medical doctor" along with the caution printed in bold type "use for any purpose not specified or not in accordance with directions and use by unauthorized persons is disapproved by the Federal Government: This substance is harmful to the environment," is not "misbranded."

ADMINISTRATOR'S ORDER REGARDING DDT

Order. Before the Environmental Protection Agency. In regard: Stevens Industries, Inc., et al. (Consolidated DDT Hearings), I.F. & R. Docket No. 63 et al.

In accordance with the foregoing opinion, findings and conclusions of law, use of DDT on cotton, beans (snap, lima, and dry), peanuts, cabbage, cauliflower, brussel sprouts, tomatoes, fresh market corn, garlic, pimentoes, in commercial greenhouses, for mothproofing and control of bats and rodents are hereby canceled as of December 31, 1972.

Use of DDT for control of weevils on stored sweet potatoes, green peppers in the Del Marva Peninsula and cutworms on onions are canceled unless within 30 days users or registrants move to supplement the record in accordance with Part V of my opinion of today. In such event the order shall be stayed, pending the completion of the record, on terms and conditions set by the Hearing Examiner: *Provided*, That this stay may be dissolved if interested users or registrants do not present the required evidence in an expeditious fashion. At the conclusion of such proceedings, the issue of cancellation shall be resolved in accordance with my opinion today.

Cancellation for uses of DDT by public health officials in disease control programs and by USDA and the military for health quarantine and use in prescription drugs is lifted.

In order to implement this decision no DDT shall be shipped in interstate commerce or within the District of Columbia or any American territory after December 31, 1972, unless the label bears in a prominent fashion in bold type and capital letters, in a manner satisfactory to the Pesticides Regulation Division, the following language:

> (1) For use by and distribution to only U.S. Public Health Service Officials or for distribution by or on approval by the U.S. Public Health Service to other Health Service Officials for control of vector diseases; (2) For use by and distribution to the USDA or Military for Health Quarantine Use; (3) For use in the formulation for prescription drugs for controlling body lice; (4) or in drugs for use in controlling body lice—to be dispensed only by physicians.
>
> Use by or distribution to unauthorized users or use for a purpose not specified hereon or not in accordance with directions is disapproved by the Federal Government: This substance is harmful to the environment.

The Pesticides Regulation Division may require such other language as it considers appropriate.

This label may be adjusted to reflect the terms and conditions for shipment for use on green peppers in Del Marva, cutworms on onions, and weevils on stored sweet potatoes if a stay is in effect.

Dated: June 2, 1972.

WILLIAM D. RUCKELSHAUS.

[FR Doc.72-10340 Filed 7-6-72;8:50 am]

APPENDIX B

that imposition of the death sentence cannot stand after Furman v. Georgia, *supra*, which was decided after his sentencing. In the light of *Furman* the Government has recognized that a sentence of death under 22 D.C.Code § 2404 is illegal and has suggested that No. 72-1711 be remanded to the District Court for resentencing only as to Tony Lee's three convictions for first-degree murder. The Court agrees.

Accordingly, these cases are affirmed in all respects and No. 72-1711 is remanded for resentencing.

It is so ordered.

ENVIRONMENTAL DEFENSE FUND, INC., et al., Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY and William D. Ruckelshaus, Administrator, Respondents,

Coahoma Chemical Company, Inc., Intervenors.

ENVIRONMENTAL DEFENSE FUND, INC., Petitioners,

v.

ENVIRONMENTAL PROTECTION AGENCY and William D. Ruckelshaus, Administrator, Respondents.

COAHOMA CHEMICAL COMPANY et al., Petitioners,

v.

William D. RUCKELSHAUS, Administrator, Environmental Protection Agency, Respondent,

EDF et al., Intervenors.

OLIN CORPORATION, Petitioner,

v.

William D. RUCKELSHAUS, Administrator, Environmental Protection Agency, Respondent.

CAROLINA CHEMICALS, INC., et al., Petitioners,

v.

William D. RUCKELSHAUS, Administrator, Environmental Protection Agency, Respondent.

W. R. GRACE & CO. et al., Petitioners,

v.

William D. RUCKELSHAUS, Environmental Protection Agency, Respondent.

OCTAGON PROCESS, INC., Petitioner,

v.

William D. RUCKELSHAUS, Administrator of the Environmental Protection Agency, Respondent.

Nos. 72-1548, 72-1690, 72-2142, 72-2183, 73-1015, 73-1088, 73-2070.

United States Court of Appeals, District of Columbia Circuit.

Argued Nov. 5, 1973.

Decided Dec. 13, 1973.

Petitions for review of order of the Environmental Protection Agency which cancelled almost all registrations for use of DDT except for limited public health and agricultural pest quarantine purposes. The Court of Appeals, Wilkey, Circuit Judge, held that such order was supported by substantial evidence when record as a whole was considered, and that even though action of Environmental Protection Agency would have a substantial effect on human environment, filing of a specific report was not required under the National Environmental Policy Act of 1969.

Affirmed.

1. Agriculture ⟹9

Provisions for judicial review under both 1970 and 1972 Federal Insecticide, Fungicide and Rodenticide Acts require court to determine whether findings of fact of the Administrator of Environmental Protection Agency are based upon substantial evidence when considered on record as a whole. Federal Insecticide, Fungicide and Rodenticide Act, § 4(c, d), 7 U.S.C.A. § 135b(c, d); Federal Environmental Pesticide Control Act of 1970, §§ 2(bb), 3(c)(5)(D), 7 U.S.C.A. §§ 136(bb), 136a(c)(5)(D).

2. Health and Environment 🔑25.5

"Substantial evidence," for purposes of reviewing findings of fact of Administrator of Environmental Protection Agency, means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion. Federal Insecticide, Fungicide and Rodenticide Act, § 4(c, d), 7 U.S.C.A. § 135b(c, d); Federal Environmental Pesticide Control Act of 1970, §§ 2(bb), 3(c)(5)(D), 7 U.S.C.A. §§ 136(bb), 136a(c)(5)(D).

See publication Words and Phrases for other judicial constructions and definitions.

3. Administrative Law and Procedure 🔑676

Health and Environment 🔑25.5

Hearing examiner's findings and opinion are to be considered as part of evidence of record, both by Administrator of Environmental Protection Agency and by reviewing court.

4. Health and Environment 🔑25.5

Even though Administrator of Environmental Protection Agency decided contrary to conclusions of hearing examiner, the administrator gave sufficient weight to hearing examiner's report, where the administrator reviewed report of examiner and exceptions to report filed by Environmental Protection Agency staff, the administrator decided case on basis of record developed in the hearings, additional briefs, oral argument, and specially prepared summaries, and case was one where demeanor of witnesses was not particularly important and where examiner himself had no particular expertise.

5. Agriculture 🔑9

Order of Administrator of Environmental Protection Agency which cancelled, effective December 31, 1972, almost all registrations for use of DDT, except for limited public health and agricultural pest quarantine purposes, was supported by substantial evidence, when record as a whole was considered. Federal Insecticide, Fungicide and Rodenticide Act, §§ 2-13, 4(c, d), 7 U.S.C.A. §§ 135-135k, 135b, (c, d); Federal Environmental Pesticide Control Act of 1970, §§ 2(bb), 3(c)(5)(D), 7 U.S.C.A. §§ 136(bb), 136a(c)(5)(D); Reorganization Plan No. 3 of 1970, 5 U.S.C.A. App.

6. Health and Environment 🔑25.10

Even though action of Environmental Protection Agency in withdrawing DDT registrations would have a substantial effect on human environment, filing of a specific report was not required under the National Environmental Policy Act of 1969, where lengthy hearings were held during which public comment was solicited, and a wide scope of environmental aspects were considered, and the environmental impact of the action, possible adverse environmental effects, possible alternatives, relationship between long and short term uses and goals, and any irreversible commitments of resources all received attention during the hearings and decision-making process. National Environmental Policy Act of 1969, § 102(2)(C), 42 U.S.C.A. § 4332(2)(C).

7. Health and Environment 🔑25.5

Where an agency is engaged primarily in an examination of environmental questions, and substantive and procedural standards insure full and adequate consideration of environmental issues, formal compliance with National Environmental Policy Act of 1969 is not necessary, and functional compliance is sufficient.

* * *

John F. Dienelt, Washington, D. C., with whom William A. Butler, East Setauket, N. Y., was on the brief for petitioners in Nos. 72-1548 and 72-1690 and Environmental Defense Fund, Inc., and others, petitioners in No. 72-2142.

Robert L. Ackerly with whom Charles A. O'Connor, III, Washington, D. C., was on the brief for petitioners in Nos. 72-2142, 72-2183, 73-1015 and 73-2070.

Stephen F. Eilperin, Atty., Dept. of Justice with whom Walter H. Fleischer, Atty., Dept. of Justice and Blaine Field-

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ing, Atty., Environmental Protection Agency, were on the brief for respondents. Alan S. Rosenthal, Atty., Dept. of Justice and Michael C. Farrar, Atty., Environmental Protection Agency also entered appearances for respondents.

Charles M. Crump, Memphis, Tenn., and Walkins C. Johnston, Montgomery, Ala., were on the brief for intervenors.

Before TAMM, ROBINSON and WILKEY, Circuit Judges.

WILKEY, Circuit Judge:

Coahoma Chemical Company, the Environmental Defense Fund, and other parties seek review of the 14 June 1972 Order of the Administrator of the Environmental Protection Agency (EPA) which cancelled, effective 31 December 1972, almost all registrations for the use of DDT, except for limited public health and agricultural pest quarantine purposes.[1] Coahoma, along with other producers and users, challenges the Order as going too far in banning most uses of DDT; the Environmental Defense Fund (EDF) challenges the Order as not going far enough by allowing a few uses to remain.

I. AGENCY ACTION

After a lengthy administrative review of DDT, a potent pesticide,[2] the Order of 14 June 1972 was promulgated. The EDF first sought cancellation of DDT registrations under the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA] in October 1969.[3] More than a year later, and after two cases challenging the lack of Government action had been brought in and decided by this court,[4] on 15 January 1971[5] the Administrator of EPA issued cancellation notices for all registrations of insecticides containing DDT. However, no suspension of use was required at this time.

EPA began evidentiary hearings on DDT in August 1971. A month later an Advisory Committee, appointed at the request of the registrants (*i. e.*, users and producers) of DDT,[6] issued a report confirming the hazards caused by DDT and recommending suspension or rapid decrease in use. In one of several preliminary judicial skirmishes between the parties, this court ordered EPA to reconsider its decision not to suspend use of DDT pending the outcome of the cancellation proceedings;[7] reconsideration resulted in no change by EPA. We later in effect gave EPA a 15 April 1972 deadline before which to conduct meaningful administrative proceedings.[8]

The EPA hearings terminated in March 1972, after seven months of testimony from a broad spectrum of the public, and in April the Hearing Examiner[9] filed his Recommended Findings, Conclusions, and Orders.[10] The Hearing Examiner concluded that all cancellation notices should be withdrawn, and registrations of DDT should continue, except for non-military mothproofing and DDD fruit spray.[11]

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[1] Environmental Defense Fund (EDF) Appendix at 50.

[2] The chemical name for DDT is 1,1,1-trichloro-2,2-bis (pchlorophenyl) ethane. EDF Appendix at 105.

[3] 7 U.S.C. §§ 135–135k (1970). Originally FIFRA was enforced and administered by the Secretary of Agriculture. However, a reorganization in 1970 placed responsibility in the Administrator of EPA. *See* Reorganization Plan No. 3 of 1970, in Appendix to Title 5, U.S.C.

[4] Environmental Defense Fund v. Hardin, 138 U.S.App.D.C. 391, 428 F.2d 1093 (1970) [The court granted EDF standing to contest the failure to cancel all DDT registrations and remanded to the Secretary of Agriculture to reconsider and give reasons.]; Environmental Defense Fund v. Ruckelshaus, 142 U.S.App.D.C. 74, 439 F.2d 584 (1971) [The court directed the Administrator of EPA, now in charge of FIFRA, to initiate cancellation proceedings because of substantial questions of safety of DDT, and to reconsider suspension of use.].

[5] EPA PR Notice 71-1. Also TDE, a related chemical, suffered cancelled registrations by PR Notice 71-5.

[6] FIFRA establishes an elaborate procedure for registrants who wish to challenge proposed cancellations. Registrants may request an advisory committee of scientific experts be selected by the National Academy of Sciences to review the proposed action. Additionally, registrants may file objections and request a public hearing. 7 U.S.C. § 135b(c). Both options were utilized here.

[7] Environmental Defense Fund v. Ruckelshaus, Order (No. 71-1256, 22 Sept. 1971).

[8] Environmental Defense Fund v. Ruckelshaus, Order (No. 71-1256, 9 Dec. 1971).

The Administrator chose to review the case personally (instead of delegating this as he normally would to the Judicial Officer),[12] and after oral argument and written briefs concluded on 14 June 1972 that DDT was sufficiently dangerous to require its use to be banned for most purposes. The Administrator delayed the effective date of his Order for six months, so that users of DDT could be educated in the proper use of alternative pesticides.[13]

The statutory basis for the EPA action lies in the Federal Insecticide, Fungicide, and Rodenticide Act, FIFRA. This Act requires registration of every economic poison distributed or sold in the United States.[14] Registration is to be denied if the substance does not comply with the provisions of the Act,[15] and misbranding of the substance is a prohibited action.[16] Misbranding is defined in the statute to have occurred, "if in the case of an insecticide . . . when used as directed or in accordance with commonly recognized practice it shall be injurious to living man or other vertebrate animals, or vegetation, except weeds, to which it is applied, or to the person applying such economic poison.[17] A later formulation of this requirement was incorporated in the Federal Environmental Pesticide Control Act of 1972, which requires denial of registration unless the substance "will perform its intended function without unreasonable adverse effects on the environment,"[18] and unless "when used in accordance with widespread and commonly recognized practice it will not generally cause unreasonable adverse effects on the environment."[19] The FIFRA provisions further require that the order of the Administrator cancelling registrations must be based on substantial evidence of record developed at a hearing, if a public hearing is held, and the order must set forth detailed findings of fact.[20]

The Administrator's Order is challenged on two grounds: (1) is it based on substantial evidence in the record; (2) does it comply with the requirements of the National Environmental Policy Act (NEPA)? For the reasons explicated in Parts II and III below, to both questions our answer is affirmative.

II. JUDICIAL REVIEW OF THE ADMINISTRATOR'S ORDER

A. *The Test*

Explicitly established in the substantive legislation are the standards for judicial review. Once the Administrator has made a final order concerning the registration of a pesticide, that order is appealable to the United States Court of Appeals. The FIFRA statute directs the Court of Appeals to sustain the find-

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[9] The official title for the Hearing Examiner is now Administrative Law Judge. *See* 37 Fed.Reg. 16787 (1972); 5 C.F.R. § 930, Subpart B (1973).

[10] EDF Appendix at 100.

[11] Examiner's Proposed Orders, in EDF Appendix at 207–218.

[12] *See* Brief of Respondent, William D. Ruckelshaus, et al., at 21.

[13] *See* Brief of Petitioner, Environmental Defense Fund, et al., at 30.

[14] 7 U.S.C. § 135b(a) (1970).

[15] 7 U.S.C. § 135b(c).

[16] 7 U.S.C. § 135a(a)(5).

[17] 7 U.S.C. § 135(z)(2)(g).

[18] 7 U.S.C. § 136a(c)(5)(C) (Supp. II, 1972).

[19] 7 U.S.C. § 136a(c)(5)(D). The statute defines "unreasonable adverse effects" as "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." 7 U.S.C. § 136(bb).

[20] 7 U.S.C. § 135b(c) (1970).

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ings of the Administrator with respect to questions of fact if "supported by substantial evidence when considered on the record as a whole." [21] The 1972 amendments further elaborate the scope of judicial review:

> The court shall consider all evidence of record. The order of the Administrator shall be sustained if it is supported by substantial evidence when considered on the record as a whole.[22]

The two versions provide standards of review which are somewhat different, in that the court under the 1970 language need only support *findings of fact* by the Administrator if based on substantial evidence, but the 1972 language requires the court to support *orders* of the Administrator which are based on substantial evidence. The 1972 amendment was enacted and effective on 21 October 1972, four months after the Administrator issued his Order in question here, but well before our judicial review. While the parties seem to assume that the 1970 version is controlling for purposes of our review,[23] the 1972 statute has no provision denying application to judicial review of prior orders of the Administrator. We read the 1972 amendment as establishing a standard effective for judicial review commencing after 21 October 1972, and therefore applicable in the case at bar.

[1, 2] In any event, the provisions for judicial review under both the 1970 and 1972 language clearly require the court to determine whether the findings of fact of the Administrator are based upon substantial evidence when considered on the record as a whole. Thus we must apply a traditional type of substantial evidence test, albeit one based on an extraordinarily voluminous record.[24] "Substantial evidence" was long ago defined by Chief Justice Hughes as "more than a mere scintilla. It means such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." Consolidated Edison Co v. NLRB.[25] And since the statute requires the whole record to be considered as in Universal Camera Corp. v. NLRB:

> The substantiality of evidence must take into account whatever in the record fairly detracts from its weight. . . . . [This does not mean] that even as to matters not requiring expertise a court may displace the Board's choice between two fairly conflicting views, even though the court would justifiably have made a different choice had the matter been before it *de novo*.[26]

The Supreme Court has more recently recognized in Consolo v. Federal Maritime Commission that there may be inconsistent conclusions which can be drawn from the same record, each of which may be supported by substantial evidence. Thus, "substantial evidence"

> is something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.[27]

The Supreme Court went on to point out that the substantial evidence test "frees the reviewing courts of the time-consuming and difficult task of weighing the evidence, it gives proper respect to the expertise of the administrative tribunal and it helps promote the uniform application of the statute." [28] Other courts have stressed that where questions involve a special expertise of an agency, such as in detailed scientific proceedings, the agency deserves special deference from the courts, although careful review is of course always required.[29]

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[21] 7 U.S.C. § 135b(d) (1970).

[22] 7 U.S.C. § 136n(b) (Supp. II, 1972).

[23] Brief of Petitioner, Coahoma Chemical Co., at 15; Brief of Petitioner, EDF, at 32.

[24] During seven months of hearings, 125 witnesses appeared to testify and 365 exhibits were placed in evidence. The transcript of the hearings was over 9,000 pages long. Brief of Petitioner, Coahoma Chemical Co., at 5.

[25] 305 U.S. 197, 229, 59 S.Ct. 206, 217, 83 L.Ed. 126 (1938).

[26] 340 U.S. 474, 488, 71 S.Ct. 456, 464, 95 L.Ed. 456 (1951).

[27] 383 U.S. 607, 620, 86 S.Ct. 1018, 1027, 16 L.Ed.2d 131 (1966).

In the case at bar our task is made somewhat simpler than the agency's by adhering conscientiously to the proper scope of judicial review of administrative action, *i. e.*, we as a court are confronted with a problem in administrative law, not in chemistry, biology, medicine, or ecology. It is the administrative agency which has been called upon to hear and evaluate testimony in all scientific fields relevant to its ultimate question of permission or prohibition of the sale and use of DDT. The EPA Administrator had an opportunity to make a careful study of the record of seven months of public hearings and the summaries of evidence prepared for him,[30] heard oral argument, and now has arrived at a decision to ban most uses of DDT. It is *his* decision which we must review; we are not to make the same decision ourselves. We are concerned with how he did it and on how much evidence. Since there is no challenge to procedure here, our problem narrows down to whether his decision is supported by substantial evidence based on the record as a whole.

B. *The Evidence*

A review of the evidence in this case, as summarized by all the briefs, indicates that the situation is as described in *Consolo*: there is a great mass of often inconsistent evidence which was developed at the hearing; this evidence is substantial enough to support the conclusions of the Administrator, although it possibly might support contrary conclusions as well. Considering the evidence in the record as a whole, we cannot say that the Administrator's decision was not based on substantial evidence, even if the hazardous nature of DDT has not been proved beyond a reasonable doubt. Sufficient evidence has been adduced to show potentially great dangers from DDT, and the Administrator's decision to cancel the DDT registrations is well within his statutory authority.

Specifically, the Administrator states that DDT is hazardous because of several of its inherent properties: its persistence, mobility, and lipid solubility.[31] He contends that the alternatives to DDT do not have such properties, although he concedes that the alternatives may be more acutely toxic in the short run. He presents detailed evidence concerning the human hazards which may arise from DDT (carcinogenicity and mutagenicity of DDT), and also details the environmental hazards (effects on phytoplankton, beneficial agricultural insects, aquatic invertebrates, fish, and birds).[32] He concludes that an unacceptable risk to man and his environment is posed by continued use of DDT,[33] aside from the few carefully controlled uses concerning public health and agricultural quarantine purposes, which he permits.[34]

These findings and the evidence on which they are based are vigorously challenged by Coahoma and other DDT users. While their evidence might be sufficient to have allowed the Administrator to have decided the other way, and permit DDT to continue, their evi-

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[28] *Ibid.*

[29] *See, e. g.*, Deutsch v. United States Atomic Energy Commn., 130 U.S.App.D.C. 339, 401 F.2d 404 (1968).

[30] The public disclosure of these summaries is sought under the Freedom of Information Act, 5 U.S.C. § 552 (1970), in a companion case, Montrose Chemical Corp. v. Ruckelshaus, Nos. 73-1443 and 73-1444.

[31] *See* Brief of Respondent, Ruckelshaus, at 28-43.

[32] *See id.* at 43-85.

[33] *See id.* at 86.

[34] *See id.* at 106.

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dence is not sufficient to vitiate the actual decision of the Administrator as not having been based on substantial evidence in the record as a whole.

[3] Since the Administrator here decided contrary to the conclusions of the Hearing Examiner, the question arises concerning the proper deference to be given to the Hearing Examiner's report. As the Supreme Court indicated in *Universal Camera*, the hearing examiner's findings and opinion are to be considered as part of the evidence of record, both by the Administrator and by the reviewing court.

> We do not require that the examiner's findings be given more weight than in reason and in the light of judicial experience they deserve. The "substantial evidence" standard is not modified in any way when the Board and its examiner disagree. We intend only to recognize that evidence supporting a conclusion may be less substantial when an impartial, experienced examiner who has observed the witnesses and lived with the case has drawn conclusions different from the Board's than when he has reached the same conclusion. . . . The significance of his report, of course, depends largely on the importance of credibility in the particular case.[35]

Later, in FCC v. Allentown Broadcasting Corp.[36] the Court indicated that where responsibility for decision was placed on the Board, it would be inconsistent to require the Board to adopt an examiner's findings unless rejection would be "clearly erroneous." However, the Court did not elaborate on the proper standard to be applied. Subsequently in an opinion by Judge Tamm in Cinderella Career and Finishing Schools, Inc. v. FTC, this Circuit held that the agency or administrator deciding a case "must consider [the decision of the examiner] and the evidence in the record upon which it is based, rather than dismissing the proceedings at the hearing out of hand."[37]

[4] Applying the law to the facts at hand, we conclude that the Administrator has given sufficient weight to the hearing examiner's report. The Administrator reviewed the report of the examiner and the exceptions to the report filed by the EPA staff. He decided the case on the basis of the record developed at the hearings, additional briefs, oral argument, and specially prepared summaries.[38] The case appears to be one where the demeanor of witnesses is not particularly important, and where the examiner himself had no particular expertise, for he was a coal mine accident specialist.[39] The Administrator could derive a proper appreciation of the effect of cross-examination in the case by a reading of the record. Thus we conclude that sufficient weight was given to the examiner's report.

In another aspect of the question of the substantiality of the evidence, Coahoma, et al., urge that the Administrator's findings are insufficient in that they are based to a large extent on data which does not directly and specifically relate to the use of DDT to combat the boll weevil and the bollworm in the cotton growing areas of the Southeast.[40] It is true that much of the evidence in the record concerning dangers of DDT does not specifically relate to this one area or to the use on cotton crops. However, it is not necessary to have evidence on such a specific use or area in order to be able to conclude on the basis of substantial evidence that the use of DDT in general is hazardous. The Administrator has pointed to evidence in the record showing that use of DDT except in minuscule amounts in highly controlled circumstances should be curtailed because of unreasonable risks to health and the environment.[41] Reliance on general data, consideration of laboratory experiments on animals, etc., provide a sufficient basis to support the Administrator's findings, even with regard to each special use of DDT.

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[35] 340 U.S. 474, 496, 71 S.Ct. 456, 469, 95 L.Ed. 456 (1951).

[36] 349 U.S. 358, 75 S.Ct. 855, 99 L.Ed. 1147 (1955).

[37] 138 U.S.App.D.C. 152, 157, 425 F.2d 583, 588 (1970).

[38] *See* note 30, *supra*.

[39] Brief of Respondent, Ruckelshaus, at 16.

[40] It appears that most of the DDT now in use in the United States is for control of cotton pests, primarily the bollworm. In fact, at least 70% of all DDT is used in the cotton-growing areas, especially the Southeast. Brief of Respondent, Ruckelshaus, at 86. The Intervenors, National Cotton Council of America, et al., suggest in their Brief at 4 that cotton accounts for an even greater percentage of use. Their figure of 90% reflects the cancellation of registrations for a variety of uses in 1969–1971.

On the other hand, EDF challenges the Administrator's decision to allow use of DDT in controlling certain public health problems or in agricultural quarantines as not being based on substantial evidence. Specifically EDF contends that there is no need to retain these uses of DDT, and that the usual dangers of DDT are present in these particular uses.[42] The Administrator finds that these uses may be necessary to combat potential, severe public health problems, and so DDT registrations for these purposes should be allowed. The necessity arises from the fact that alternative pesticides are also under EPA review, that situations may arise where the alternatives are not effective,[43] and that DDT must be available. Because the allowance of continued registration does not mean continued use, except where certified to be necessary, the Administrator concludes that the benefits of continued registration outweigh the risks inherent in such a minuscule use. This view has support in the record as a whole, and thus satisfies the substantial evidence test.

[5] The entire Order of the Administrator is supported by substantial evidence when the record as a whole is considered. Under a proper application of the substantial evidence test, as formulated by the Supreme Court and by this Circuit, we affirm the Administrator's Order. We stress again that from an administrative law perspective we simply conclude that the Administrator's Order is adequately supported by evidence in the record. We do not decide whether we, ourselves, would ban DDT, nor should we so decide. We have, however, carefully reviewed the decision of the Administrator, and conclude that it should be affirmed.

III. COMPLIANCE WITH THE NATIONAL ENVIRONMENTAL POLICY ACT OF 1969

The second challenge to the EPA's action raised by petitioners Coahoma Chemical Co., et al., concerns the failure of EPA to file a specific report under the National Environmental Policy Act of 1969 (NEPA). That statute requires that

> to the fullest extent possible . . . all agencies of the Federal Government shall . . . include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on —(i) the environmental impact of the proposed action. . . .[44]

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[41] *See* notes 32–34, *supra*. For the EPA's argument directed towards cotton pests, *see* Brief of Respondent, Ruckelshaus, at 96–99.

[42] Brief of Petitioner, EDF, at 91–92.

[43] Brief of Respondent, Ruckelshaus, at 106–107.

[44] 42 U.S.C. § 4332(2)(C) (1970). The statement is required to include consideration of

> (i) the environmental impact of the proposed action,
>
> (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented,
>
> (iii) alternatives to the proposed action,
>
> (iv) the relationship between local short-term uses of man's environment and the maintenance and enhancement of long-term productivity, and
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> (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented.

Id.

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This has been interpreted to require an agency to prepare an environmental impact statement whenever the agency's proposed action will have a significant effect on the environment.

There is little doubt but that the action of EPA in withdrawing DDT registrations will have a substantial effect on the human environment—indeed, that was the very purpose of the EPA action. The court is asked to consider two other, somewhat interrelated questions concerning NEPA. First, is the EPA an agency subject to the requirements of the statute when it undertakes environmental actions such as the cancellation of DDT registrations here? Second, has EPA in effect complied with the requirements, despite the lack of a formal NEPA impact statement?

Petitioners Coahoma Chemical Co., et al., urge that EPA is not exempted from the NEPA requirements. They stress the statutory language requiring ALL agencies to comply, and note that there is no specific language in either NEPA or FIFRA which exempts EPA in this or any other set of circumstances. They note two District Court cases which indicate that all agencies, even the environmental ones, are covered by the NEPA requirements.[45] Furthermore, they contrast the action of Congress in providing a specific exemption for EPA in the Federal Water Pollution Control Act Amendments of 1972,[46] with the absence of a provision in the 1972 FIFRA amendments enacted three days later.[47]

On the other hand, EPA contends that NEPA does not apply to the "environmentally protective regulatory activities of the Administrator conducted under the registration cancellation provision of the FIFRA."[48] Instead, EPA believes that the case is controlled by this Circuit's decision in Portland Cement Ass'n v. Ruckelshaus.[49] EPA limits its brief to the contention that NEPA does not apply to *this* type of action, although it states in footnote that perhaps NEPA is not applicable to any of EPA's environmentally protective regulatory activities.[50]

Portland Cement involved EPA's promulgation of stationary source standards for cement plants pursuant to the Clean Air Act.[51] The EPA action was challenged in part because the agency did not file a NEPA statement in conjunction with the promulgation of standards. Judge Leventhal noted that "there is a serious question whether NEPA is applicable to environmentally protective regulatory agencies. There is no express exemption in the language of the Act or Committee Reports."[52] We analyzed the pertinent legislative history, concluded that it was inconclusive, and then looked to the purpose and policies underlying NEPA. The goal of NEPA was of course to protect the environment, which it did through "a broadly applicable measure that only provides a first step."[53] In *Portland Cement* we thought that this goal might best be served by exempting certain activities from the formal requirements of filing NEPA reports. While we were not there willing to decide whether there was a broad exemption for all EPA environmental actions, we concluded that the actions taken in that case under the Clean Air Act were exempt from NEPA, because the Clean Air Act "requires the functional equivalent of a NEPA impact statement."[54] The Clean Air Act required the Administrator to supply a statement of reasons for his proposed standard, which statement should set forth the environmental considerations, both pro and con, and thus the Act seemed to "strike a workable balance between some of the advantages and disadvantages of full application of NEPA."[55] Furthermore, opportunity for public comment was provided, as was opportunity for court review.

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[45] The two cases noted by Coahoma are Kalur v. Resor, 335 F.Supp. 1 (D.D.C.1971) [re Corps of Engineers], and Anaconda v. Ruckelshaus, 352 F.Supp. 697 (D.Colo.1972) [re EPA]. The first of these cases was dismissed as moot by this Circuit. *See* Portland Cement Ass'n v. Ruckelshaus, 158 U.S.App.D.C. 308, 318 n. 41, 486 F.2d 375, 385 n. 41 (1973). The second case was observed by us in *Portland Cement* to have a "myopic" view. *Ibid.*

[46] 33 U.S.C. § 1371(c) (Supp. II, 1972).

[47] The FIFRA amendments are contained in the Federal Environmental Pesticide Control Act of 1972, 7 U.S.C. § 136 (Supp. II, 1972). A similar argument was put forth in the *Portland Cement* case, but was dismissed by the court there as providing a "hazardous basis for inferring the intent of the earlier Congress." 158 U.S.App.D.C. at 315, 486 F.2d at 382, citing to United States v. Southwestern Cable Co., 392 U.S. 157, 170, 88 S.Ct. 1994, 20 L.Ed.2d 1001 (1968).

[48] Supplemental Brief of Respondent Ruckelshaus, at 2.

[49] 158 U.S.App.D.C. 308, 486 F.2d 375 (1973).

[50] Supplemental Brief of Respondent, Ruckelshaus, at 2–3, n. 1. The EDF supports the limited stand of EPA. Supplemental Brief of Petitioner, EDF, at 13.

[51] 42 U.S.C. § 1857c–6 (1970).

[52] 158 U.S.App.D.C. at 314, 486 F.2d at 381.

[6] The rationale we first developed in *Portland Cement* is applicable here as well, and an exemption from the strict letter of the NEPA requirements is thus appropriate. The explicit language in FIFRA requires that pesticides be deregistered if they will be injurious to man and his environment. The substantive standard established by the statute places great emphasis on the quality of man's environment. Additionally, the procedural standards provide full opportunity for thorough consideration of the environmental issues, and for ample judicial review. In this particular case, lengthy hearings were held, during which public comment was solicited, and a wide scope of environmental aspects were considered. Thus the functional equivalent of a NEPA investigation was provided, for all of the five core NEPA issues were carefully considered: the environmental impact of the action, possible adverse environmental effects, possible alternatives, the relationship between long- and short-term uses and goals, and any irreversible commitments of resources—all received attention during the hearings and decision-making process.[56] The law requires no more.

When it is clear that the NEPA objections are being raised by parties who have had ample opportunity to express their views,[57] when there has been functional compliance, the *Portland Cement* rationale should certainly apply, and the agency action should be exempted from the strict letter of NEPA requirements. As we wrote recently, "To require a 'statement,' in addition to a decision setting forth the same considerations would be a legalism carried to the extreme."[58]

Our recent decision in Arizona Public Service Co. v. FPC,[59] which requires an

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[53] *Id.* at 316, 486 F.2d at 383.

[54] *Id.* at 317, 486 F.2d at 384.

[55] *Id.* at 319, 486 F.2d at 386.

[56] *See* note 44, *supra.*

[57] As EPA points out, the NEPA objection was only first raised in the briefs to this court; in none of the earlier proceedings was any mention made of NEPA requirements. The raising of the objection so late in the proceedings makes the Coahoma position look more like a delaying tactic than a real concern with the environment. However, our recent decision in Arizona Public Service Co. v. FPC, 157 U.S.App.D.C. 272, 280, 483 F.2d 1275, 1283 (1973), noted that "the tardiness of the parties cannot excuse an agency from complying with its responsibilities under NEPA."

[58] International Harvester Co. v. Ruckelshaus, 155 U.S.App.D.C. 411, 446, 478 F.2d 615, 650 n. 130 (1973). The court in *International Harvester* noted that

> the requirements of NEPA should be subject to a "construction of reasonableness." Although we do not reach the question whether EPA is automatically and completely exempt from NEPA, we see little need in requiring a NEPA statement from an agency whose raison d'être is the protection of the environment and whose decision on suspension is necessarily infused with the environmental considerations so pertinent to Congress in designing the statutory framework.

Ibid.

[59] 157 U.S.App.D.C. 272, 483 F.2d 1275 (1973).

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agency to at least file a statement of reasons as to why an impact statement is not necessary,[60] is inapposite to the case at bar. In *Arizona Public Service* the Federal Power Commission did not look carefully at the environmental questions, but merely concluded in one sentence that there was no environmental impact.[61] That is a far cry from the instant case, where the whole focus of the agency action has been on the environmental aspects of the use of DDT. The reason for the failure to file a formal NEPA impact statement need not be explicitly stated here, for it is apparent on the face of the agency's action.

[7] We conclude that where an agency is engaged primarily in an examination of environmental questions, where substantive and procedural standards ensure full and adequate consideration of environmental issues, then formal compliance with NEPA is not necessary, but functional compliance is sufficient. We are not formulating a broad exemption from NEPA for all environmental agencies or even for all environmentally protective regulatory actions of such agencies. Instead, we delineate a narrow exemption from the literal requirements for those actions which are undertaken pursuant to sufficient safeguards so that the purpose and policies behind NEPA will necessarily be fulfilled. The EPA action here meets this standard, and hence this challenge to the EPA action is rejected.

IV. CONCLUSION

On review of the decision and Order of the EPA Administrator, we find it to be supported by substantial evidence based on the record as a whole. Furthermore, we find that EPA has provided the functional equivalent of a formal NEPA report. Therefore, the two challenges raised concerning the Administrator's decision to cancel DDT registrations are rejected and the Administrator's action is affirmed.

NATIONAL REALTY AND CONSTRUCTION COMPANY, INC.,
Petitioner,
v.
OCCUPATIONAL SAFETY AND HEALTH REVIEW COMMISSION, Respondent,
Secretary of Labor, Party Respondent.
No. 72-1978.

United States Court of Appeals,
District of Columbia Circuit.
Argued Oct. 24, 1973.
Decided Dec. 13, 1973.

Proceeding on petition for review of order of the Occupational Safety and Health Review Commission which found that employer committed a serious violation of the general duty clause of the Occupational Safety and Health Act. The Court of Appeals, J. Skelly Wright, Circuit Judge, held that in absence of showing of the particular steps employer should have taken to avoid citation for permitting employee to stand as a passenger on running board of front-end loader at construction site, and the feasibility and likely utility of those measures, finding of violation was not supported by substantial evidence.

Reversed.

1. Labor Relations ⟸27

Labor Secretary's burden of proving violations of the general duty clause of the Occupational Safety and Health Act includes burden of persuading the commission, or its hearing examiner, by a preponderance of the evidence. Occupational Safety and Health Act of 1970, § 5(a)(1), 29 U.S.C.A. § 654(a)(1).

2. Labor Relations ⟸27

Reviewing court must uphold Occupational Safety and Health Review Commission finding of violation of general duty clause of Occupational Safety and Health Act supported by substantial evi-

APPENDIX C

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yment tax and wishes to enter into e Standard Agreement as set out in Subpart C shall, by a letter addressed to the Fiscal Assistant Secretary, Department of the Treasury, Washington, D.C. 20220, signed by an appropriate city official, state its agreement to be bound by all of the provisions of the Standard Agreement set forth below. Copies of all applicable city ordinances, regulations, instructions, and forms shall be enclosed. The letter shall also state the title and address of the official whom the agencies may contact to obtain forms and other information necessary to implement withholding.

(b) Within 120 days of the receipt of the letter from the city official, the Fiscal Assistant Secretary or his designee will by letter notify the city either (1) that the Standard Agreement has been entered into as of the date of the Fiscal Assistant Secretary's letter, or (2) that an agreement cannot be entered into with the city and the reasons for that determination.

§ 215.4 Procedure for agreement other than Standard Agreement.

(a) If a city which has an ordinance which provides for a city income or employment tax proposes an agreement which varies from the Standard Agreement, the city shall follow the procedure in § 215.3, except that its letter shall state which provisions of the Standard Agreement are not acceptable, propose substitute provisions, and give the reasons therefor.

(b) Within 60 days, the Fiscal Assistant Secretary or his designee will notify the city which substitute provisions may be included in the agreement. The city shall, by letter, notify the Fiscal Assistant Secretary if it accepts such an agreement. When accepted by the city, the effective date of that agreement shall be the date such acceptance is received by the Fiscal Assistant Secretary.

Subpart C—Standard Agreement Text

§ 215.5 Parties.

The parties to this agreement are the Secretary of the Treasury, acting through his designee, and the city which has entered into this agreement pursuant to §§ 215.3 or 215.4.

§ 215.6 Compliance by agencies.

Except as otherwise provided in this agreement, the head of each agency of the United States shall comply with all ordinances of the city which provide for a city income or employment tax, and all regulations and procedural instructions issued thereunder, with respect to employees of the agency who are subject to the tax and whose regular place of Federal employment is within the political boundaries of the city.

15.7 Employee withholding certificates.

Each agency may require its employees to complete a withholding certificate as the basis for calculating the amount to be withheld regularly from each employee's compensation. The agency may rely on the information in the certificate, unless it is contrary to information in the possession of the agency. The agency may use the certificate which the city has prescribed, if any, or any other certificate, approved by the Department of the Treasury, which the agency finds suitable. Copies of such certificates will be provided to cities by agencies upon request.

§ 215.8 Agency withholding procedures.

(a) Where it is the practice of an agency to file returns and make payments of the Federal income taxes withheld on an estimated basis subject to later adjustments based on audited figures, such practice may be followed in the withholding of city income and employment taxes if the agency has made appropriate arrangements with the city.

(b) In calculating the amount to be withheld from an employee's compensation, each agency shall use the method prescribed by the city, or any percentage or formula method which produces approximately the tax required to be withheld by the city ordinance.

(c) Procedures for the withholding, the filing of returns, and the payment of tax to the city shall conform to the usual fiscal practices of agencies.

(d) Federal Form W-2, "Wage and Tax Statement," may be used by agencies for the reporting of withheld taxes to the city.

(e) Agencies shall not withhold the city income or employment tax from the unpaid compensation of a deceased employee.

§ 215.9 Miscellaneous provisions.

(a) This agreement does not (1) allow agencies to collect delinquent city taxes or penalties from Federal employees, (2) apply to pay for service as a member of the Armed Forces, or (3) permit the withholding of city income or employment taxes from the pay of a Federal employee who is not a resident of the State in which the city is located unless the employee consents to the withholding.

(b) Agencies may not accept pay from the city for services performed in withholding the city income or employment tax.

§ 215.10 Amendment cancellation.

This agreement is subject to the provisions of 5 U.S.C. 5520 and other applicable laws, and any rules or regulations issued thereunder, including amendments to such provisions occurring after the effective date of this agreement. The Secretary or his designee may, after giving 30 days notice to the city, amend or waive any part of this agreement. Either the Secretary or his designee or the city may cancel this agreement after giving 30 days written notice to the other party.

§ 215.11 Effective date; commencement of withholding.

(a) The effective date of this agreement shall be:

(1) In the case of a city accepting all of the provisions of this agreement, the date of the letter to the city from the Fiscal Assistant Secretary of the Treasury or his designee stating that the agreement has been entered into, or

(2) In the case of an agreement which varies from this Standard Agreement, the date that the Fiscal Assistant Secretary receives the letter from the city accepting the Department's determination as to the inclusion of such variations.

(b) The withholding of the city income or employment tax shall commence within 90 days after the effective date of this agreement.

Dated: March 13, 1975.

[SEAL] JOHN K. CARLOCK,
Fiscal Assistant Secretary.

[FR Doc.75-7034 Filed 3-17-75;8:45 am]

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

[FRL 344-4]

PART 164—RULES OF PRACTICE GOVERNING HEARINGS, UNDER THE FEDERAL INSECTICIDE, FUNGICIDE AND RODENTICIDE ACT, ARISING FROM REFUSALS TO REGISTER, CANCELLATIONS OF REGISTRATIONS, CHANGES OF CLASSIFICATIONS, SUSPENSIONS OF REGISTRATIONS AND OTHER HEARINGS CALLED PURSUANT TO SECTION 5 OF THE ACT

Subpart D—Rules of Practice for Applications Under Sections 3 and 18 To Modify Previous Cancellation or Suspension Orders

On February 10, 1975, the Environmental Protection Agency ("EPA") published notice in the FEDERAL REGISTER (40 FR 6229) of the filing of an application under section 18 of the Federal Insecticide, Fungicide and Rodenticide Act, as amended ("FIFRA"), and regulations thereunder, for the use of pesticides containing DDT (1,1,1-trichlorophenyl ethane) on cotton to control the tobacco bud worm. EPA also published on February 10, 1975, notice in the FEDERAL REGISTER (40 FR 6228) of informal public hearings with respect to Louisiana's application to be held in Baton Rouge, Louisiana, on February 27-28, 1975 and in Washington, D.C., on March 3-5, 1975.

The objective of EPA in holding these informal hearings was to provide all interested parties with an opportunity informally to present their views and to allow EPA to reach a determination as soon as practicable. As these informal hearings progressed it became apparent that the questions raised by the Louisiana application directly relate to the prior cancellation determination of the Administrator with respect to DDT, following extensive adjudicatory hearings and judicial review. After the informal hearings were announced, concern developed within EPA that because of these prior administrative and judicial proceedings, informal hearings alone may not fully satisfy the requirements of the FIFRA, the Administrative Procedures Act and due process. EPA has concluded that the law requires that revised procedures be instituted for the

Louisiana application and for similar cases in the future, in order to provide required notice and opportunity for formal public hearings to all affected parties. If the procedures were not revised and the ultimate determination were to grant the petition, court challenges to the procedures would cause additional delays and may even result in reversal on procedural grounds. In such a situation, Louisiana would be denied the benefits of a favorable ruling for spring cotton planting because of procedural irregularities. The purpose of this notice is to set forth the required procedures and to explain reasons for requiring such procedures. With respect to the Louisiana application this notice also serves to confirm a tentative time schedule announced at the Washington, D.C. informal hearings on March 5, 1975, within which these procedures will operate.

Since the registration of DDT for pests on cotton, including the tobacco bud worm, constituted at least 75% of DDT usage subject to the cancellation order of the Administrator of June 14, 1972 (37 FR 13369) and amounted to 10 million pounds of DDT annually, the Louisiana application for use of 2.25 million pounds in Louisiana in 1975 squarely presents the question of whether the final cancellation order should be reconsidered. EPA has determined that any application under section 3 or section 18 of FIFRA for the use of a pesticide at a site and on a pest for which registration has been finally cancelled or suspended by the Administrator is in substance a petition for reconsideration of such order. Because of the extensive notice and hearing opportunities mandated by FIFRA and the Administrative Procedures Act before a final cancellation or suspension order may be issued, EPA has determined that such orders may not be reversed or modified without affording interested parties—who may in fact have participated in lengthy cancellation proceedings—similar notice and hearing opportunities.

Section 6 of FIFRA permits the Administrator to issue notice of intent to cancel a pesticide registration upon a finding by him that the pesticide "generally causes unreasonable adverse effects on the environment. "Such notice is required to be sent to the registrant and made public. The registrant, or other person adversely affected, may then request a hearing. The final decision of the Administrator is required to be made after the conclusion of the hearing. The United States Court of Appeals for the District of Columbia has characterized the cancellation procedures as providing "extensive safeguards" and "elaborate procedural protection" to pesticide registrants and others and, as a result, "a substantial time, likely to exceed one year, may lapse between issuance of notice of cancellation and final order of cancellation. * * *" *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 326 F.2d 528, 533 (1972).

The application filed by Louisiana involves the requested use of DDT on cotton. The extensive administrative and judicial proceedings leading up to final cancellation of DDT registrations not only relate directly to the Louisiana petition but also demonstrate the exhaustive proceedings which precede final EPA actions in contested cancellation or suspension proceedings.

PROCEEDINGS LEADING TO THE FINAL CANCELLATION OF DDT

(1) *The EDF Petition of October 1969.* On October 31, 1969, the Environmental Defense Fund, The National Audubon Society, the Sierra Club and the West Michigan Environmental Action Counsel ("EDF") filed a petition with the Secretary of Agriculture ("USDA"), requesting him (1) to issue notices of cancellation for all pesticide products containing DDT, and (2) to suspend the registrations during the cancellation proceedings. EDF's petition precipitated, as the Administrator's Order noted, "approximately 3 years of intensive administrative inquiry into the uses of DDT." Order of June 14, 1972 at 1 ("Order").

(2) *The Secretary of Agriculture's Response.* In response to EDF's petition, three things occurred. First, USDA cancelled four uses of DDT (on shade trees, tobacco, around the home and in aquatic areas); second, USDA requested comments on other DDT products; and third, USDA took no action on the request for suspension.

On November 25, 1969, USDA published a notice which stated (34 FR 18827):

> The department is considering cancellation of any other uses of DDT unless it can be shown that certain uses are essential in the protection of human health and welfare and only those uses for which there are no effective and safe substitutes for the intended use will be continued.

On December 11, 1969, a reply to the petition was sent to EDF by the Director of Science and Education for USDA, stating that the Department had been "concerned for some time over the potential hazards that may result from the presence of DDT and other persistent pesticides in the environment," and listing several actions, including the above cancellations, that had been taken. No specific mention was made of EDF's request for suspension.

(3) *Environmental Defense Fund, Inc.* v. *Hardin (DDT I)*. On December 29, 1969, EDF filed a petition in the Court of Appeals for the District of Columbia seeking review of USDA's failure to comply fully with their requests.

On May 28, 1970, in *Environmental Defense Fund, Inc.* v. *Hardin*, 138 U.S. App. D.C. 391, 428 F.2d 1093 (1970), the Court held that EDF had standing to challenge the Secretary's determinations under FIFRA, that a refusal to suspend was reviewable, and that the inaction on the suspension request was ripe for review. This Court noted that:

> Numerous scientific studies and seve reports to government agencies have cc cluded that DDT has a wide spectrum harmful effects on nontarget plant and a mal species; it increases the incidence animals of cancer and reproductive defec and its residues persist in the environme and in the human body long enough to found far in time and space from the origir application. 428 F.2d at 1096–97.

and remanded to the Secretary:

> *Either for a fresh determination on t question of suspension, or for a statement reasons for his silent but effective refu to suspend the registration of DDT. If persists in denying suspension in the fa of the impressive evidence presented by pet tioners, then the basis for that decisio should appear clearly on the record, not conclusory terms but in sufficient detail permit prompt and effective review. 428 F.2 at 1100.*

In addition, the Court ordered USDA t decide "on the record" whether to issu the remaining requested cancellatio notices or to explain the reasons fo deferring the decision still further. *Ibid*

(4) *The "Statement of Reasons" o the Secretary and Additional Cancella tions.* On June 23, 1970, the Secretar filed a "Statement of Reasons Underly ing the Decisions on Behalf of the Sec retary with Respect to the Registration of Products Containing DDT." At th outset he adhered to "the prior determination that no DDT registration should be suspended at this time, and that further action with respect to cancellations should await completion of (USDA's intra-agency) use-by-use evaluations presently in progress." Statement of Reasons at 1. He went on to make the following findings:

> (1) "that there are reports of carcinogenicity resulting from the administration of large doses of DDT in test animals" (p. 1);
>
> (2) DDT is persistent and accumulates in animal tissues (p. 3);
>
> (3) "DDT is present in most forms of animal life" (ibid.);
>
> (4) "there is information which suggests that DDT is interfering with the reproduction of certain raptorial birds and may be a contributor, among other factors, to the decline of some of these species" (*ibid.*);
>
> (5) "DDT is moderately toxic to honey bees" (*ibid.*);
>
> (6) "DDT in lakes and streams has been a factor in fish mortality and reproductive failures" (*ibid.*); and
>
> (7) When DDT accumulates in "detritus food some harm may be done to detritus feeders" (pp. 3–4).

He concluded (p. 8) that:

> (1) DDT is not an "imminent hazard to human health";
>
> (2) "there are some adverse effects upon certain species of fish and wildlife";
>
> (3) "DDT has indisputably important and beneficial uses in connection with human health and agriculture, and there are not yet available substitutes for *all* [emphasis added] essential uses";
>
> (4) DDT use should be reduced to "uses which are essential to the public health and welfare"; and
>
> (5) there should be "continuation of the review of the possible effects (both beneficial and deleterious) of DDT."

In addition to issuing the Secretary's statement of reasons, USDA took other ction subsequent to the filing of EDF's itial petition. Specifically, on February , May 6 and August 18, 1970, in order protect man and the environment om the hazardous use of DDT, notices of cancellation were issued covering registrations for a number of vegetable, grain, fruit, forestry, livestock, nursery and lawn uses of products containing DDT.

(5) *Environmental Defense Fund v. Ruckelshaus (DDT II)*. On January 7, 1971, after reviewing USDA's Statement of Reasons, the Court remanded the case a second time, this time to the Administrator of the newly-created Environmental Protection Agency, who had just been given authority for administration of the FIFRA. *Environmental Defense Fund v. Ruckelshaus*, 142 U.S. App. D.C. 74, 439 F. 2d 584 (1971).

The Court determined that the Secretary's refusal to suspend or cancel all registrations of DDT had been predicated on an "incorrect interpretation of the controlling statute." 439 F. 2d at 588. Noting in particular that the Secretary had found that DDT at large dosages caused cancer in experimental animals and that DDT was toxic to certain birds, bees, and fish, the Court stated that it was "plain that he found a substantial question concerning the safety of DDT." 439 F. 2d at 594-95. When such a question exists, this Court held, the administrative procedure must be "triggered." Accordingly, the case was remanded to the Administrator with instructions to ue notices of cancellation with respect he remaining uses of DDT.

(6) *The Administrator's Issuance of Notices of Cancellation*. On January 15, 1971, the Administrator issued notices of cancellation with respect to all remaining registrations of DDT products.

More than 50 registrants filed objections and a request for a public hearing. Two registrants, Montrose Chemical Company and Crop King sought advisory committee consideration. In addition to EDF, several other parties intervened in the hearing, namely: USDA, The National Agricultural Chemicals Association (NACA), H. P. Cannon & Son (a Delaware food processor, only as to use of DDT on sweet peppers) and Eli Lilly & Company, a former registrant of one DDT product. Montrose and Crop King were not parties to the public hearing.

(7) *The Administrator's March 18, 1971 Refusal to Suspend*. In response to Court order that he reconsider the question of suspension, the Administrator issued a statement of "Reasons Underlying the Registration Decisions Concerning Products Containing DDT, 2,4,5-T, Aldrin and Dieldrin" on March 18, 1971. It set forth the reasons why the Administrator deemed suspension of DDT products unnecessary in view of the administrative proceeding then underway, and articulated general standards relating to pesticide cancellation and suspension matters. The Administrator noted that:

> is determination is supported by the re of the present effects of DDT. DDT hazard by virtue of its potential toxicity prolonged low levels of exposure. This azard is made acute by the persistence, mobility, and biomagnification of DDT in the environment. Recognizing these characteristics, the four government committees which have studied the DDT problem in depth between 1963 and 1969 have all recommended that its use be phased out over a period of time. [Footnote omitted] None have recommended an immediate ban. However, the time has come for resolution of the DDT issue in light of the standards set out in the FIFRA. This is now being done through the orderly administrative forum provided by the statute in the cancellation proceedings.

(8) *Advisory Committee Report*. The advisory committee requested by Crop King and Montrose, and composed of experts nominated by the National Academy of Sciences, began deliberations on DDT in May, 1971. On September 9, 1971, the committee issued its report and recommendations. After a lengthy discussion of the scientific evidence of the hazards of DDT use, the committee found that DDT posed an imminent hazard to the environment and recommended that all DDT uses be rapidly phased out. Previously, four Presidential and other scientific commissions recognized the inherent hazards of DDT. "Use of Pesticides," A Report of the President's Science Advisory Committee (May, 1963); "Restoring the Quality of Our Environment," Report of the Environmental Pollution Panel, President's Science Advisory Committee (November, 1965); Report of the Committee on Persistent Pesticides, Division of Biology and Agriculture, National Research Council, to U.S. Department of Agriculture (May 1969); the Report of the (H.E.W.) Secretary's Commission on Pesticides and Their Relationship to Environmental Health (Mrak Commission) (December, 1969).

(9) *EDF v. Ruckelshaus (DDT III)*. EDF returned to Court a third time to challenge the Administrator's refusal to suspend. Since the advisory committee report was issued just prior to oral argument, the case was remanded to EPA for further consideration of the suspension issue in light of the advisory committee findings.

(10) *The Administrator's November 1, 1971 Statement*. In a statement filed with the Court on November 1, 1971, the Administrator again determined not to suspend DDT products. In reaching that decision he noted that the advisory committee had found:

> DDT spreads from its site of application and is carried 'throughout the global biosphere' (Conclusion 2, page 39); and DDT and its metabolites persist for years in the environment and become concentrated in certain species of fish and wildlife, which suffer either present or potential danger therefrom (Conclusion 3, page 39).

However, the Administrator concluded, as the advisory committee had similarly concluded,

> * * * there will be no appreciable difference in hazard to the public whether the registration of DDT is immediately suspended or whether it is cancelled in the near future, if warranted. Therefore, the harm to the public from DDT cannot be lessened by immediate suspension as opposed to appropriate cancellations upon the orderly completion of the cancellation procedures.

(11) *EDV v. Ruckelshaus (DDT IV)*. With the administrative proceedings in process, the Court on December 9, 1971, denied EDF's suspension petition, while at the same time granting EDF the right to renew its petition if the administrative proceedings were not completed by April 15, 1972.

(12) *Formal Public Hearings*. Formal public hearings commenced on August 17, 1971, before a hearing examiner and concluded on March 16, 1972. During those eight months, 123 witnesses[1] testified, and 363 exhibits were introduced into evidence. The DDT industry presented 17 witnesses and introduced 58 exhibits; USDA, in a dual role as registrant (of two agricultural pest quarantine products) and intervenor, presented 40 witnesses and 94 exhibits; EDF presented 13 witnesses and introduced 68 exhibits; and the EPA staff presented 47 witnesses and introduced 132 exhibits. The remaining witnesses and exhibits were introduced by H. P. Cannon and Eli Lilly. The transcript of the evidentiary hearing contains more than 9,300 pages.

(13) *The Examiner's Recommended Decision*. The Hearing Examiner's recommended decision was issued on April 25, 1972. Stating that in order to cancel DDT, he would either have to find that DDT directly causes cancer in man or makes the "earth uninhabitable" the Examiner concluded that the "DDT products in issue were not misbranded under the FIFRA (7 U.S.C. 135b(2), (z)(2) (c), (d) and (g))"; that, as a matter of law, DDT use is not a carcinogenic, mutagenic or teratogenic hazard to man; and that DDT did not have a deleterious effect on fish or wildlife. Rec. Dec. pp. 92–94.

(14) *Oral Argument Before the Administrator*. On May 16, 1972, the Administrator personally heard over three hours of oral argument on the exceptions raised by the various parties.

(15) *The Administrator's Cancellation Order of June 14, 1972*. On June 14, 1972, the Administrator issued an order cancelling all DDT registrations except those for public health and agricultural pest quarantine use. The order established December 31, 1972, as the effective date of the cancellations.

At the outset, he stated that he was "persuaded * * * that the long-range risks of continued use of DDT for use on cotton and most other crops is unacceptable and outweighs any benefits." Order at 1.

The Administrator found that DDT is persistent, highly mobile in the environment, biomagnified in food chains, and has deleterious effects on beneficial organisms. The bulk of his Opinion and Findings were concerned with the harmful effects resulting from these properties and assessment of the asserted bene-

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[1] 38 of the witnesses were wildlife biologists, 32 were entomologists, 9 were toxicologists or pharmacologists, 5 were cancer experts, 6 were chemists, 5 were medical doctors, 2 were economists, and 6 were businessmen. The remaining witnesses represented other miscellaneous disciplines and fields.

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fits of the DDT uses in issue. He found that DDT is a potential human carcinogen and presents a real carcinogenic risk to man. See Findings at 3.

He also found widespread hazards to birds, fish and other animal life caused by use of DDT, specifically (*ibid*):

1. DDT affects phytoplankton species' composition and the natural balance in aquatic ecosystems.
2. DDT is lethal to many beneficial agricultural insects.
3. DDT can have lethal and sublethal effects on useful aquatic freshwater invertebrates, including arthropods and molluscs.
4. DDT is toxic to fish.
5. DDT can affect the reproductive success of fish.
6. DDT can have a variety of sublethal physiological and behavioral effects on fish.
7. Birds can mobilize lethal amounts of DDT residues.
8. DDT can cause thinning of bird eggshells and thus impair reproductive success.

He then found minimal benefits because adequate alternative pest control measures were available. Finding V-10. He ultimately concluded that almost all uses of DDT were not safe, that the risks of use far outweighed any benefits and that it was therefore misbranded under FIFRA.

(16) *EDF v. EPA (DDT V)*. Coahoma Chemical Company, EDF and other parties sought review of the Administrator's final cancellation order in the Court of Appeals. Observing that the order was issued "after a lengthy administrative review. . . ," the Court affirmed the determination and order of the Administrator. *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 489 F. 2d 1247, 1249 (D.C. Cir. 1973). In so doing the Court rejected industry argument that:

> * * * the Administrator's findings are insufficient in that they are based to a large extent on data which does not directly and specifically relate to the use of DDT to combat the boll weevil and the bollworm in the cotton growing areas of the Southeast.

The Court went on to find that:

> It is true that much of the evidence in the record concerning dangers of DDT does not specifically relate to this one area or to the use on cotton crops. However, it is not necessary to have evidence on such a specific use or area in order to be able to conclude on the basis of substantial evidence that the use of DDT in general is hazardous. The Administrator has pointed to evidence in the record showing that use of DDT except in minuscule amounts in highly controlled circumstances should be curtailed because of unreasonable risks to health and the environment. Reliance on general data, consideration of laboratory experiments on animals, etc., provide a sufficient basis to support the Administrator's findings, even with regard to each special use of DDT. 489 F.2d at 1253-54 (footnotes omitted).

Other Cancellation and Suspension Proceedings. In each of the other major cancellation and suspension proceedings initiated pursuant to Section 6, EPA has similarly provided extensive notice and formal hearing opportunities.

The aldrin and dieldrin suspension order issued by the Administrator on October 1, 1974 followed almost three years of administrative proceedings. The initial cancellation notice for the major uses of aldrin and dieldrin was issued by the Administrator on March 18, 1971. Formal administrative hearings commenced on August 7, 1973. During the following twelve months of hearing, 249 witnesses testified, and over 35,000 pages of transcript and exhibits were considered and the suspension is now subject to judicial review by the Court of Appeals for the District of Columbia.

Similarly, the two administrative proceedings currently in progress with respect to pesticide products containing mercury and mirex have involved lengthy hearings. The notice of intent to hold hearings on mirex was issued on March 23, 1973. The formal hearings were begun on December 3, 1973 and have not yet concluded. To date, over 60 witnesses have testified in those hearings resulting in a record of over 12,400 pages. As in the aldrin and dieldrin proceedings, a scientific advisory committee report on mirex was prepared prior to the commencement of the formal hearings.

The cancellation notice of pesticide products containing mercury was issued on March 22, 1972. The formal administrative hearings began on October 1, 1974 and are still in progress. Forty witnesses have testified thus far in those hearings generating a record of over 2,400 pages.

THE REQUIRED PROCEDURES

In cancellation and suspension cases such as those outlined above, where EPA has finally determined to cancel or suspend a pesticide registration after exhaustive notice and opportunities for hearing as mandated by FIFRA and the Administrative Procedure Act ("APA"), fairness requires that such final orders not be modified or reversed lightly. Such prior orders should not be modified or reversed without notice and opportunity for formal public hearings. The formal on-the-record decision making process imposed by FIFRA and the APA as a necessary prerequisite to final cancellation or suspension would be rendered meaningless if the Administrator were to modify or reverse such orders without notice to the public, without an opportunity for formal hearings and without limiting his consideration to a formal hearing record. Such an informal process could greatly prejudice the interests of parties to the original proceedings. In the original proceedings they had the opportunity to be represented by counsel, to present witnesses and documentary evidence and to cross-examine witnesses of other parties. They had the opportunity to argue their cases before an independent hearing examiner and before the Administrator. An informal process to modify or reverse final orders would not prove such opportunities, would not protect the procedural rights of affected persons and would undercut the statutory scheme required by FIFRA.

Formal reconsideration of prior orders should only be granted where there is substantial new evidence which may materially affect the order. The provisions of FIFRA relating to notice and opportunity of adversely affected to join in formal hearings are b drafted to permit maximum par tion in the cancellation proceedi other Federal agencies, the States, try, environmental groups, and p citizens. With such broad opporti to participate in the original procee the public interest—and the intere the parties who participated in suc ceedings—requires that the issues the Administrator not be relit without a threshold determination there is substantial new evidence may materially affect the prior This procedure does not prejudic interests of parties seeking modific If there is substantial new eviden formal hearing should be convene demonstrate the materiality of such dence. Moreover, the public interes mands that public agencies not be quired to expend limited resource reconsideration of facts previously a dicated. Public resources should no committed to reconsider a prior fina der unless there is substantial new dence which may materially affect order.

For the foregoing reasons, EP adopting a new Subpart D to the R of Practice (40 CFR Part 164) set forth the procedures to be followe the case of an application under FI sections 3 or 18 which requests use pesticide at a site and on a pest for wh registration has been finally cance or suspended. These revised procedu require that in any such case the Adm istrator will initially determine, on basis of the application and support data, whether there is substantial n evidence which may materially affect prior order and whether such evide could not have been discovered by d diligence on the part of the parties the original proceeding. If it is dete mined that there is no such eviden then the application will be denied. If is determined that there is such eviden then a formal hearing will be conve to determine whether such evidence m terially affects the prior order and r quires its modification. This determin tion will be made on the basis of the re ord in the hearing and the recommend tions of the administrative law jud presiding over the hearing, taking in account the human and environmen risks found by the Administrator in h prior order and the cumulative impa of past, present, and anticipated uses the future. The procedures adopted to day also provide that in emergency cir cumstances the Administrator may ru on the application without convening formal hearing when he determin that: (1) the application presents a sit uation involving need to use the pesticid to prevent an unacceptable risk to (i) human health, or (ii) fish and wildlif when such use would not pose a huma health hazard; and (2) there is no other feasible alternative solution to such risk; and (3) the time available to avert the risk to human health or fish and wildlife is insufficient to permit convening a hearing; and (4) the public interest requires the granting of the requested use soon as possible.

Notice of the Administrator's determinations regarding substantial new evidence will be published in the FEDERAL REGISTER, as will notice of findings of emergencies which require action without hearing.

In the case of the petition by the State of Louisiana it is anticipated that the Administrator will make his determination as to whether substantial new evidence exists on or about March 14, 1975. If it is determined that no substantial new evidence is presented then the petition will be denied. If it is determined that substantial new evidence is presented then notice of a formal public hearing will be issued as soon as possible and it is anticipated that, depending on the date of the Administrator's determination, the hearing would commence on March 21, 1975, and be scheduled for approximately five days, with the presiding officer's recommendations due approximately four to five days after the hearing and a final determination by the Administrator anticipated to be made approximately four to five days thereafter. Notice of the revised procedures set forth in this publication and of this tentative time schedule was given to all parties involved in the informal public hearings held in Washington, D.C., on March 5, 1975. Because of the March 5, 1975 notice to interested parties, including the State of Louisiana, the publication of this regulation on the eve of the Administrator's anticipated decision as to substantial new evidence will not prejudice the interests of interested parties including the State of Louisiana. All interested parties received notice of these procedures on March 5 and were encouraged to submit an additional brief statement summarizing what they maintain to be substantial new evidence on March 10, 1975. The State of Louisiana, and other interested parties have submitted such statements.

In addition, the Louisiana application was filed under FIFRA section 18 pursuant to which Louisiana is required to show that there is a pest outbreak for which no alternatives are available and which will result in significant economic or health problems (40 CFR Part 166). Louisiana has questioned whether EPA is now changing the substantive standard by which its application will be evaluated. The procedures set forth in this regulation do not, however, change the substantive rules by which the Louisiana application will be measured. The issues raised by the Louisiana application under section 18 were adjudicated and finally decided in the 1972 DDT cancellation case. In that case the Administrator was required to make, and made, specific findings and conclusions with respect to the risks and benefits associated with DDT use on cotton. The Administrator's findings and conclusions were then affirmed by the Court of Appeals for the District of Columbia. Thus, no showing under section 18 of a pest outbreak, of unavailability of alternatives and of significant economic problems could now be made without substantial new evidence. The procedures set forth in this regulation clarify the application of the general rules under sections 3 and 18 to specific cases such as the Louisiana application, which in substance request modification or reversal of a prior final order.

Following the 1972 DDT cancellation order, EPA permitted limited quantities of DDT for temporary use to control the pea leaf weevil and the tussock moth in specific areas. In 1973 and 1974 DDT was authorized for use for the pea leaf weevil in Idaho and Washington. These authorizations considered the available evidence "in light of the terms of the June 1972 (cancellation) order * * *." (39 FR 10322). However, the use of DDT for the pea leaf weevil was not cancelled by the Administrator in his 1972 order and thus the pea leaf weevil applications did not in substance request the use of a pesticide on a site and against a pest which was cancelled by final order.

In 1974 DDT was authorized for use on the Douglas-fir tussock moth in Oregon, Idaho and Washington. That decision specifically stated that: "The use of DDT for control of the tussock moth was not specifically addressed in (the 1972 DDT cancellation) order, but there is no present registration of DDT for this purpose." 39 FR 8377. The use of DDT on the Douglas-fir tussock moth was not cancelled by the Administrator in his 1972 order. This use had been registered in 1947 by the Forest Service, but the registration was later withdrawn without objection.

To the extent that the procedures announced in this notice may differ from prior agency practice as observed in the pea leaf weevil, tussock moth and other cases, EPA has concluded that such differences are necessitated for the reasons set forth in this preamble.

In accordance with 5 U.S.C. section 553, the procedures set forth in these regulations shall take effect upon publication, without notice and public procedure thereon, because they contain rules of agency procedure and practice which are not required to be issued as proposed rulemaking. For the reasons set forth in this preamble, EPA finds for good cause that the effective date of these regulations will not be postponed for 30 days after publication because the currently pending application by the State of Louisiana requests a determination as soon as possible and EPA has determined that these procedures should be implemented immediately so that the Louisiana application may be processed in accordance with them.

For the reasons set forth herein, Title 40, Part 164 of the Code of Federal Regulations is hereby amended by adding a new Subpart D to read as follows:

Dated: March 12, 1975.

RUSSELL E. TRAIN,
Administrator.

Subpart D—Rules of Practice for Applications Under Sections 3 and 18 To Modify Previous Cancellation or Suspension Orders

Sec.
164.130 General.
164.131 Review By Administrator.
164.132 Procedures governing hearing.
164.133 Emergency waiver of hearing.

AUTHORITY: Sec. 25(a) and 6 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended by the Federal Environmental Pesticide Control Act of 1972 (86 Stat. 907).

Subpart D—Rules of Practice for Applications Under Sections 3 and 18 To Modify Previous Cancellation or Suspension Orders

§ 164.130 General.

EPA has determined that any application under section 3 or section 18 of the Act to allow use of a pesticide at a site and on a pest for which registration has been finally cancelled or suspended by the Administrator constitutes a petition for reconsideration of such order. Because of the extensive notice and hearing opportunities mandated by FIFRA and the Administrative Procedures Act before a final cancellation or suspension order may be issued, EPA has determined that such orders may not be reversed or modified without affording interested parties—who may in fact have participated in lengthy cancellation proceedings—similar notice and hearing opportunities. The procedures set forth in this Subpart D shall govern all such applications.

§ 164.131 Review by Administrator.

(a) The Administrator will review applications subject to this Subpart D and supporting data submitted by the applicant to determine whether reconsideration of the Administrator's prior cancellation or suspension order is warranted. The Administrator shall determine that such reconsideration is warranted when he finds that: (1) the applicant has presented substantial new evidence which may materially affect the prior cancellation or suspension order and which was not available to the Administrator at the time he made his final cancellation or suspension determination and (2) such evidence could not, through the exercise of due diligence, have been discovered by the parties to the cancellation or suspension proceeding prior to the issuance of the final order.

(b) If after review of the application and other supporting data submitted by the applicant, the Administrator determines, in accordance with paragraph (a), of this section, that reconsideration of his prior order is not warranted, then the application will be denied without requirement for an administrative hearing. The Administrator shall publish notice in the FEDERAL REGISTER of the denial briefly describing the basis for his determination as soon as practicable. Such denial shall constitute final agency action.

(c) If after review of the application and other supporting data submitted by the applicant, the Administrator deter-

[illegible] in accordance with paragraph (a) of this section, that reconsideration of his prior order is warranted, he will then publish notice in the FEDERAL REGISTER setting forth his determination and briefly describing the basis for the determination. Such notice shall announce that a formal public hearing will be held in accordance with 5 U.S.C. section 554. The notice shall specify: (1) the date on which the hearing will begin and end, (2) the issues of fact and law to be adjudicated at the hearing, (3) the date on which the presiding officer shall submit his recommendations, including findings of fact and conclusions, to the Administrator, and (4) the date on which a decision by the Administrator is anticipated.

§ 164.132 Procedures governing hearing.

(a) The burden of proof in the hearing convened pursuant to § 164.131 shall be on the applicant and he shall proceed first. The issues in the hearing shall be whether: (1) substantial new evidence exists and (2) such substantial new evidence requires reversal or modification of the existing cancellation or suspension order. The determination of these issues shall be made taking into account the human and environmental risks found by the Administrator in his cancellation or suspension determination and the cumulative effect of all past and present uses, including the requested use, and uses which may reasonably be anticipated to occur in the future as a result of granting the requested reversal or modification. The granting of a particular petition for use may not in itself pose a significant risk to man or the environment, but the cumulative impact of each additional use of the cancelled or suspended pesticide may re-establish, or serve to maintain, the significant risks previously found by the Administrator.

(b) The presiding officer shall make recommendations, including findings of fact and conclusions and to the extent feasible, as determined by the presiding officer, the procedures at the hearing shall follow the Rules of Practice, set forth in Subparts A and B of this Part 164.

§ 164.133 Emergency waiver of hearing.

(a) In the case of an application subject to this Subpart D which is filed under Section 18 of FIFRA, and regulations thereunder, and for which a hearing is required pursuant to § 164.131, the Administrator may dispense with the requirement of convening such a hearing in any case in which he determines:

(1) That the application presents a situation involving need to use the pesticide to prevent an unacceptable risk: (i) to human health, or (ii) to fish or wildlife populations when such use would not pose a human health hazard; and

(2) That there is no other feasible solution to such risk; and

(3) That the time available to avert the risk to human health or fish and wildlife is insufficient to permit convening a hearing as required by § 164.131; and

(4) That the public interest requires the granting of the requested use as soon as possible.

(b) Notice of any determination made by the Administrator pursuant to paragraph (a) of this section shall be published in the FEDERAL REGISTER as soon as practicable after granting the requested use and shall set forth the basis for the Administrator's determination.

[FR Doc.75-7080 Filed 3-17-75;8:45 am]

Title 45—Public Welfare

CHAPTER XV—FUND FOR THE IMPROVEMENT OF POSTSECONDARY EDUCATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

PART 1501—SUPPORT FOR IMPROVEMENT OF POSTSECONDARY EDUCATION

Pursuant to the authority contained in Section 404 of the General Education Provisions Act (20 U.S.C. 1221d), "Support for improvement of postsecondary education", a notice of proposed rule making was published in the FEDERAL REGISTER on December 2, 1974 (Vol. 39, No. 232). The amendments to the regulations, reflected in §§ 1501.2-3, 1501.5-7, 1501.9-11, would: (a) redefine the special focus program objectives and establish national projects competitions; (b) revise the existing definitions and criteria for the review and selection of applications and preapplications; and (c) incorporate appropriate sections of the Office of Education's General Provisions Regulations (45 CFR Part 100a) and revoke some corresponding provisions in the existing regulations. Interested persons were given thirty (30) days in which to submit written comments, suggestions, or objections regarding the proposed amendments.

One response was received which included two recommendations: (1) that the Fund include examples of projects that have not been funded in order to clarify the criteria for selecting proposals; and (2) that the Fund not include reference to "attitudes and values" in section 1501.9 under the description of the Special Focus Program, "Education and Certification for Competence."

Neither suggestion would appear to call for a change in the amendments. In response to the first recommendation, it was not considered appropriate to include in the FEDERAL REGISTER examples of projects which have not been funded. The Fund's program is designed to generate ideas from the field; no specific types of project proposals are foreclosed.

In response to the second recommendation, the mention of "attitudes and values" as a possible goal specification is only suggestive; applicants are under no obligation or requirement to include attitudes or values among the goals included in the project proposal. It should be noted that the Fund has no specific attitude or value in mind as desirable goal specifications.

Effective date. The notice of pr rulemaking was transmitted to C on December 2, 1974 pursuant to 431(d) of the General Educatio visions Act (20 U.S.C. 1232(a)) time period set forth therein fo gressional action has expired w such action having been taken. fore, these criteria shall become ef on March 18, 1975.

(Federal Domestic Assistance Catalog 13.538: Fund for the Improvement of secondary Education)

Dated: March 12, 1975.

CASPAR W. WEINBERGER,
Secretary of Health, Education
and Wel

Sec.
1501.1 Purpose.
1501.2 Applicability of civil rights sions and general provisions lations.
1501.3 Definitions.
1501.4 Eligibility for assistance.
1501.5 Types of assistance.
1501.6 Program categories.
1501.7 Criteria for evaluating applicat
1501.8 Comprehensive program objec
1501.9 Special focus program and nat project objectives.
1501.10 Application procedures.
1501.11 Reporting.

AUTHORITY: Sec. 404, General Educa Provisions Act, as added by sec. 301(a) (2 Public Law 92-318, 86 Stat. 327 (20 U 1221d), unless otherwise noted.

§ 1501.1 Purpose.

The purpose of the regulations in part is to implement the provisions section 404 of the General Educat Provisions Act as amended which p vides for grants to, and contracts w institutions of postsecondary educat and other public and private educatio institutions and agencies to impro postsecondary educational opportuniti The program is administered by the Fu for the Improvement of Postseconda Education, a unit within the Office of t Assistant Secretary for Education of t Department of Health, Education, an Welfare, with the advice of a Board Advisors.

(20 U.S.C. 1221d)

§ 1501.2 Applicability of civil righ provisions and general provision regulations.

(a) *Civil rights*

(1) Federal financial assistance unde this part is subject to the regulations i part 80 of this title, issued by the Secretary of Health, Education, and Welfar and approved by the President, to effectuate the provisions of title VI of the Civil Rights Act of 1964 (Pub. L. 88-352).

(2) Federal financial assistance under this part is also subject to the provisions of title IX of the Education Amendments of 1972 (prohibition of sex discrimination), and any regulations issued thereunder.

(b) *General provisions*

Assistance under this part is subject to the provisions set forth in Parts 100 and 100a of this title (relating to fiscal,

APPENDIX D

[FRL 356-2]

STATE OF LOUISIANA REQUEST FOR EMERGENCY USE OF DDT ON COTTON

Statement of Reasons for Denial

Statement of Reasons for the Order and Determination of the Administrator that Reconsideration of the Agency's Prior Order of Cancellation of DDT for Use on Cotton is Not Warranted.

On January 24, 1975, the State of Louisiana applied to the Environmental Protection Agency (EPA) for a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) for the application of 2.25 million pounds of DDT (1,1,1-trichlorophenyl ethane) to control the tobacco budworm (*Heliothis virescens F.*) on approximately 450,000 acres of cotton. On February 10, 1975, EPA published notice in the FEDERAL REGISTER (40 FR 6229) of the filing of this application and notice (40 FR 6228) of informal public hearings with respect to the application to be held in Baton Rouge, Louisiana, on February 27-28, 1975 and in Washington, D.C., on March 3-5, 1975. On March 14, 1975, I issued a brief Order and Determination denying the Louisiana request and stated that a more detailed statement would follow on March 17, 1975. This Statement of Reasons provides a more detailed explanation of the basis for my Order.

I. *The Application.* The application filed by Louisiana states that the requested 2.25 million pounds of DDT is necessary because:

1. Average cotton yields have declined significantly in 1973-4 compared with the average cotton yield for the previous ten (10) years when DDT was available;

2. In 1974, Louisiana experienced its worst tobacco budworm infestation in history and the budworm is anticipated to be a major problem in 1975;

3. Tobacco budworm populations exhibit resistance to most of the alternative registered pesticides which are either ineffective, phytotoxic or unavailable in sufficient quantities and no other alternative means of control are available;

4. Serious economic injuries will result to cotton farmers and supportive industries from the tobacco budworm if DDT is not made available; and

5. Restrictions on the method and timing of application will prevent adverse environmental effects.

II. *Background.* The background of the Louisiana application and the use of DDT on cotton has been set forth in detail in the preamble to the regulations promulgated by EPA on March 12, 1975, establishing a new Subpart D of the Rules of Practice for Applications Under sections 3 and 18 to Modify Previous Cancellation or Suspension Orders. However, because of the importance to this case of the background information set forth in that document, I feel compelled to refer to that information in this Statement.

The purpose of the February 27-28 and March 3-5 informal public hearings on the Louisiana application was to provide all interested parties with an opportunity informally to present their views and to provide EPA with information necessary in order to reach a determination as soon as practicable. As these informal hearings progressed it became apparent that the questions raised by the Louisiana application directly related to the prior final order of the Administrator cancelling virtually all registered uses of DDT, including use on cotton, following extensive adjudicatory hearings and judicial review.[1] Because of these prior administrative and judicial proceedings, concern developed within EPA shortly after the announcement of the informal hearings that revised procedures may be required in order to satisfy the requirements of the FIFRA, the Administrative Procedure Act (APA) and due process. Following an analysis of the question, EPA concluded that the law and the public interest required that such revised procedures be instituted for the Louisiana application and for similar cases in the future, in order to provide required notice and opportunity for formal public hearings to all affected parties where substantial new evidence is presented which may materially affect a prior final order.

The registration of DDT for pests on cotton, including the tobacco budworm, constituted approximately 86 percent[2] of the almost 12 million pounds of DDT used in the U.S. prior to the cancellation order of the Administrator of June 14, 1972 (37 FR 13369) (hereinafter the "1972 Order"). At that time DDT use on cotton amounted to approximately 10.3 million pounds annually. The Louisiana application seeks the use of 2.25 million pounds in Louisiana this year, which amounts to approximately 19 percent of the total annual quantity of DDT used in the U.S. prior to cancellation and approximately 22 percent of the total annual quantity of DDT used on cotton in the U.S. prior to cancellation. Accordingly, the Louisiana application squarely presents the question of whether the final cancellation order should be reconsidered.

EPA has determined that any application under section 3 or section 18 of FIFRA for the use of a pesticide at a site and on a pest for which registration has been finally cancelled or suspended by the Administrator is in substance a petition for reconsideration of such order. Certainly, the Louisiana application, which requests relatively large quantities of DDT for a use which was the primary use prior to cancellation, is in substance a request for such reconsideration. Because of the extensive notice and hearing opportunities mandated by FIFRA and the APA before a final cancellation or suspension order may be issued, EPA has determined that such orders may not be reversed or modified without affording interested parties—who may in fact have participated in lengthy cancellation proceedings—similar notice and hearing opportunities where substantial new evidence exists which warrants such reconsideration.

Section 6 of FIFRA permits the Administrator to issue notice of intent to cancel a pesticide registration upon a finding by him that the pesticide "generally causes unreasonable adverse effects on the environment." Such notice is required to be sent to the registrant and made public. The registrant, or other person adversely affected, may then request a hearing. The final decision of the Administrator is required to be made after the conclusion of the hearing. The United States Court of Appeals for the District of Columbia has characterized the cancellation procedures as providing "extensive safeguards" and "elaborate procedural protection" to pesticide registrants and others and, as a result, "a substantial time, likely to exceed one year, may lapse between issuance of notice of cancellation and final order of cancellation. * * *" *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 328 F. 2d 528, 533 (1972).

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[1] Use of DDT by public health officials in disease control programs and by other civilian and military officials for health quarantine were not cancelled.

[2] The National Cotton Council of America contended that DDT use on cotton accounted for 99 percent of the total use immediately prior to the 1972 Order because of the prior cancellation of certain minor uses.

The application filed by Louisiana involves the requested use of DDT on cotton. The extensive administrative and judicial proceedings leading up to final cancellation of DDT registrations not only relate directly to the Louisiana petition but also demonstrate the exhaustive proceedings which precede final EPA actions in contested cancellation or suspension proceedings.

A. Proceedings Leading to the Final Cancellation of DDT.

(1) The EDF Petition of October 1969. On October 31, 1969, the Environmental Defense Fund, The National Audubon Society, the Sierra Club and the West Michigan Environmental Action Counsel (EDF) filed a petition with the Secretary of Agriculture (USDA), requesting him (1) to issue notices of cancellation for all pesticide products containing DDT, and (2) to suspend the registrations during the cancellation proceedings. EDF's petition precipitated, as the Administrator's 1972 Order noted, "approximately 3 years of intensive administrative inquiry into the uses of DDT." 1972 Order, 37 FR at 13369.

(2) The Secretary of Agriculture's Response. In response to EDF's petition, three things occurred. First, USDA cancelled four uses of DDT (on shade trees, tobacco, around the home and in aquatic areas); second, USDA requested comments on other DDT products; and third, USDA took no action on the request for suspension.

On November 25, 1969, USDA published a notice which stated (34 FR 18827):

> The department is considering cancellation of any other uses of DDT unless it can be shown that certain uses are essential in the protection of human health and welfare and only those uses for which there are no effective and safe substitutes for the intended use will be continued.

On December 11, 1969, a reply to the petition was sent to EDF by the Director of Science and Education for USDA, stating that the department had been "concerned for some time over the potential hazards that may result from the presence of DDT and other persistent pesticides in the environment," and listing several actions, including the above cancellations, that had been taken. No specific mention was made of EDF's request for suspension.

(3) *Environmental Defense Fund, Inc.* v. *Hardin* (*DDT I*). On December 29, 1969, EDF filed a petition in the Court of Appeals for the District of Columbia seeking review of USDA's failure to comply fully with their requests.

On May 28, 1970, in *Environmental Defense Fund, Inc.* v. *Hardin*, 428 F. 2d 1093 (1970), the Court held that EDF had standing to challenge the Secretary's determinations under FIFRA, that a refusal to suspend was reviewable, and that the inaction on the suspension request was ripe for review. This Court noted that:

> Numerous scientific studies and several reports to government agencies have concluded that DDT has a wide spectrum of harmful effects on nontarget plant and animal species; it increases the incidence in animals of cancer and reproductive defects; and its residues persist in the environment and in the human body long enough to be found far in time and space from the original application. 428 F. 2d at 1096–97.

The Court remanded to the Secretary:

> either for a fresh determination on the question of suspension, or for a statement of reasons for his silent but effective refusal to suspend the registration of DDT. If he persists in denying suspension in the face of the impressive evidence presented by petitioners, then the basis for that decision should appear clearly on the record, not in conclusory terms but in sufficient detail to permit prompt and effective review. 428 F. 2d at 1100.

In addition, the Court ordered USDA to decide "on the record" whether to issue the remaining requested cancellation notices or to explain the reasons for deferring the decision still further. Ibid.

(4) The "Statement of Reasons" of the Secretary and Additional Cancellations. On June 29, 1970, the Secretary filed a "Statement of Reasons Underlying the Decisions on Behalf of the Secretary with Respect to the Registrations of Products Containing DDT." At the outset he adhered to "the prior determination that no DDT registrations should be suspended at this time, and that further action with respect to cancellations should await completion of [USDA's intra-agency] use-by-use evaluations presently in progress." Statement of Reasons at 1. He went on to make the following findings:

> (1) that there are reports of carcinogenicity resulting from the administration of large doses of DDT in test animals (p. 1);
>
> (2) DDT is persistent and accumulates in animal tissues (p. 3);
>
> (3) DDT is present in most forms of animal life (ibid.);
>
> (4) there is information which suggests that DDT is interfering with the reproduction of certain raptorial birds and may be a contributor, among other factors, to the decline of some of these species (ibid.);
>
> (5) DDT is moderately toxic to honey bees (ibid.);
>
> (6) DDT in lakes and streams has been a factor in fish mortality and reproductive failures (ibid.); and
>
> (7) When DDT accumulates in detritus food some harm may be done to detritus feeders (pp. 3–4).

He concluded (p. 8) that:

> (1) DDT is not an imminent hazard to human health;
>
> (2) there are some adverse effects upon certain species of fish and wildlife;
>
> (3) DDT has indisputably important and beneficial uses in connection with human health and agriculture, and there are not yet available substitutes for all essential uses;
>
> (4) DDT use should be reduced to "uses which are essential to the public health and welfare"; and
>
> (5) there would be continuation of the review of the possible effects (both beneficial and deleterious) of DDT.

In addition to issuing the Secretary's statement of reasons, USDA took other action subsequent to the filing of EDF's initial petition. Specifically, on February 26, May 6 and August 18, 1970, in order to protect man and the environment from the hazardous use of DDT, notices of cancellation were issued covering registrations for a number of vegetable, grain, fruit, forestry, livestock, nursery and lawn uses of products containing DDT.

(5) *Environmental Defense Fund* v. *Ruckelshaus* (*DDT II*). On January 7, 1971, after reviewing USDA's Statement of Reasons, the Court remanded the case a second time, this time to the Administrator of the newly-created Environmental Protection Agency, who had just been given authority for administration of FIFRA. *Environmental Defense Fund* v. *Ruckelshaus*, 439 F. 2d 584 (1971).

The Court determined that the Secretary's refusal to suspend or cancel all registrations of DDT had been predicated on an "incorrect interpretation of the controlling statute." 439 F. 2d at 588. Noting in particular that the Secretary had found that DDT at large dosages caused cancer in experimental animals and that DDT was toxic to certain birds, bees, and fish, the Court stated that it was "plain that he found a substantial question concerning the safety of DDT." 439 F. 2d at 594–95. When such a question exists, the Court held, the administrative procedure must be "triggered." Although benefits may be balanced against risks, the Court held that such balancing must occur "in the full light of a public hearing * * * [and] greater weight should be accorded the value of a pesticide for the control of disease, and less weight should be accorded its value for the protection of a commercial crop." 439 F. 2d at 594 (emphasis added). Accordingly, the DDT case was remanded to the Administrator with instructions to issue notices of cancellation with respect to the remaining uses of DDT.

(6) The Administrator's Issuance of Notices of Cancellation. In compliance with the Court's order in *DDT II*, on January 15, 1971, the Administrator issued notices of cancellation with respect to all remaining registrations of DDT products.

More than 50 registrants filed objections and a request for a public hearing. Two registrants, Montrose Chemical Company and Crop King sought advisory committee consideration. In addition to EDF, several other parties intervened in the hearing, namely: USDA, The National Agricultural Chemicals Association (NACA), H. P. Cannon & Son (a Delaware food processor, only as to use of DDT on sweet peppers) and Eli Lilly & Company, a former registrant of one DDT product. Montrose and Crop King were not parties to the public hearing.

(7) The Administrator's March 18, 1971 Refusal to Suspend. In response to Court Order in *DDT II* that he reconsider the question of suspension, the Administrator issued a statement of "Reasons Underlying the Registration Decisions Concerning Products Containing DDT, 2,4,5–T, Aldrin and Dieldrin" on March 18, 1971. It set forth the reasons why the Administrator deemed suspension of DDT

products unnecessary in view of the administrative proceeding then underway, and articulated general standards relating to pesticide cancellation and suspension matters. The Administrator noted that:

> This determination is supported by the nature of the present effects of DDT. DDT is a hazard by virtue of its potential toxicity at prolonged low levels of exposure. This hazard is made acute by the persistence, mobility, and biomagnification of DDT in the environment. Recognizing these characteristics, the four government committees which have studied the DDT problem in depth between 1963 and 1969 have all recommended that its use be phased out over a period of time. [Footnote omitted] None have recommended an immediate ban. However, the time has come for resolution of the DDT issue in light of the standards set out in the FIFRA. This is now being done through the orderly administrative forum provided by the statute in the cancellation proceedings.

(8) Advisory Committee Report. The advisory committee requested by Crop King and Montrose, and composed of experts nominated by the National Academy of Sciences, began deliberations on DDT in May, 1971. On September 9, 1971, the committee issued its report and recommendations. After a lengthy discussion of the scientific evidence of the hazards of DDT use, the committee found that DDT posed an imminent hazard to the environmental and recommended that all DDT uses be rapidly phased out. Previously, four Presidential and other scientific commissions recognized the inherent hazards of DDT. "Use of Pesticides," A Report of the President's Science Advisory Committee (May, 1963); "Restoring the Quality of Our Environment," Report of the Environmental Pollution Panel, President's Science Advisory Committee (November, 1965); Report of the Committee on Persistent Pesticides, Division of Biology and Agriculture, National Research Council, to U.S. Department of Agriculture (May, 1969); the Report of the (H.E.W.) Secretary's Commission on Pesticides and Their Relationship to Environmental Health (Mrak Commission) (December, 1969).

(9) *EDF* v. *Ruckelshaus* (*DDT III*). EDF returned to Court a third time to challenge the Administrator's refusal to suspend DDT registrations. Since the advisory committee report was issued just prior to oral argument, the case was remanded to EPA for further consideration of the suspension issue in light of the advisory committee findings.

(10) The Administrator's November 1, 1971 Statement. In a statement filed with the Court on November 1, 1971, the Administrator again determined not to suspend DDT registrations. In reaching that decision he noted that the advisory committee had found:

> DDT spreads from its site of application and is carried "throughout the global biosphere" (Conclusion 2, page 39); and DDT and its metabolites persist for years in the environment and become concentrated in certain species of fish and wildlife, which suffer either present or potential danger therefrom (Conclusion 3, page 39).

However, the Administrator concluded, as the advisory committee had similarly concluded,

> * * * there will be no appreciable difference in hazard to the public whether the registration of DDT is immediately suspended or whether it is cancelled in the near future, if warranted. Therefore, the harm to the public from DDT cannot be lessened by immediate suspension as opposed to appropriate cancellations upon the orderly completion of the cancellation procedures.

(11) *EDF* v. *Ruckelshaus* (*DDT IV*). With the administrative proceedings in process, the Court on December 9, 1971, denied EDF's suspension petition, while at the same time granting EDF the right to renew its petition if the administrative proceedings were not completed by April 15, 1972.

(12) Formal Public Hearings. Formal public hearings commenced on August 17, 1971, before a hearing examiner and concluded on March 16, 1972. During those eight months, 123 witnesses[8] testified, and 363 exhibits were introduced into evidence. The DDT industry presented 17 witnesses and introduced 58 exhibits USDA, in a dual role as registrant (of two agricultural pest quarantine products) and intervenor, presented 40 witnesses and 94 exhibits; EDF presented 13 witnesses and introduced 66 exhibits; and the EPA staff presented 47 witnesses and introduced 132 exhibits. The remaining witnesses and exhibits were introduced by H. P. Cannon and Eli Lilly. The transcript of the evidentiary hearing contains more than 9,300 pages.

(13) The Examiner's Recommended Decision. The Hearing Examiner's recommended decision was issued on April 25, 1972 Stating that in order to cancel DDT, he would either have to find that DDT directly causes cancer in man or makes the "earth uninhabitable," the Examiner concluded that the "DDT products in issue were not misbranded under the FIFRA (7 U.S.C. 135b(2), (z) (2)(c), (d) and (g))"; that, as a matter of law, DDT use is not a carcinogenic, mutagenic or teratogenic hazard to man, and that DDT did not have a deleterious effect on fish or wildlife. Recommended Decision at 92–94.

(14) Oral Argument Before the Administrator. After receiving extensive written briefs, on May 16, 1972, the Administrator personally heard over three hours of oral argument on the exceptions raised by the various parties.

(15) The Administrator's Cancellation Order of June 14, 1972. On June 14, 1972, the Administrator issued an order cancelling all DDT registrations except those for public health and agricultural pest quarantine use. The order established December 31, 1972, as the effective date of the cancellations.

At the outset, he stated that he was "persuaded . . . that the long-range risks of continued use of DDT for use on cotton and most other crops is unacceptable and outweighs any benefits." 1972 Order, 37 FR 13369.

The Administrator found that "once dispersed, DDT is an uncontrollable, durable chemical that persists in the aquatic and terrestrial environments." 1972 Order, 37 FR 13370. He concluded that DDT was "highly volatile" (37 FR 13370 n. 16) and "can vaporize from crops and soils" (37 FR at 13375); that it "can be transported by drift during aerial application" (Id. at II, A, 3(a)); and that it "can be attached to eroding soil particles" (Id. at II, A, 3(c)). The Administrator also found that DDT "can persist in the soils for years and even decades" (Id. at II, A, 1); that it "can persist in aquatic ecosystems" (Id. at II, A, 2); and that "it is occasionally found in remote areas or in ocean species, such as whales, far from any known area of application" (37 FR at 13370–71). As a result of its persistence and mobility, the Administrator found that DDT is "concentrated in organisms and transferred through food webs" (37 FR at 13375); that DDT "accumulation in the food chain and crop residues results in human exposure" (Id. at III, A, 2); and that "human beings store DDT" in their tissues (Id. at III, A, 3).

With respect to human health, the Administrator found that "DDT causes tumors in laboratory animals" (Id. at IV, A, 9(a)); that "there is some indication of metastasis" of such tumors (Id. at IV, A, 9(b)); that "tumor induction in mice is a valid warning of possible carcinogenic properties" (Id. at IV, A, 9 (c)); that there are "no adequate negative experimental studies in other mammalian species" and "no adequate human epidemiological data" (Id. at IV, A, 9 (d-e)); and that "not all chemicals show the same [laboratory] tumorigenic properties" (Id. at IV, A, 9(f)). Accordingly, the Administrator found that DDT poses a cancer risk to man. (Id. at IV, A, 9; IV, B).

The Administrator also found that DDT poses hazards to birds, fish and other animal life:

> 1. DDT affects phytoplankton species' composition and the natural balance in aquatic ecosystems.
> 2. DDT is lethal to many beneficial agricultural insects.
> 3. DDT can have lethal and sublethal effects on useful aquatic freshwater invertebrates, including arthropods and mollusks.
> 4. DDT is toxic to fish.
> 5. DDT can affect the reproductive success of fish.
> 6. DDT can have a variety of sublethal physiological and behavioral affects on fish.
> 7. Birds can mobilize lethal amounts of DDT residues.
> 8. DDT can cause thinnings of bird eggshells and thus impair reproductive success. (Id. at IV, A, 1-8).

Concerning DDT's benefits, the Administrator found that "DDT is useful for the control of certain cotton insect pests" (Id. at V,A, 1); that "cotton pests are becomming resistant to DDT" (Id at

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[8] 30 of the witnesses were wildlife biologists, 32 were entomologists, 9 were toxicologists or pharmacologists, 5 were cancer experts, 6 were chemists, 5 were medical doctors, 2 were economists, and 6 were businessmen. The remaining witnesses represented other miscellaneous disciplines and fields.

V,A, 2); and that "by using methyl parathion or other means of pest control cotton producers can generally produce satisfactory yields at acceptable cost" (Id. at V,A,4). With respect to alternative chemical pesticides, the Administrator found that "methyl parathion and other organophosphate chemicals are effective for the control of cotton pests"; that they are "less toxic to aquatic life than DDT"; that they "appear to be less 'persistent' and do not build up in the food chain"; and that "methyl parathion is acutely toxic by dermal, respiratory exposure and oral inhalation" (Id at V,A, 3). The Administrator concluded that "the use of DDT was not necessary for the production" of cotton and other specified crops. (Id. at V,B).

(16) *EDF* v. *EPA* (*DDT V*). Coahoma Chemical Company, EDF and other parties sought review of the Administrator's final cancellation order in the Court of Appeals. Observing that the order was issued "after a lengthy administrative review" and on the basis of "an extraordinarily voluminous record" the Court found that the 1972 Order was supported by substantial evidence and affirmed. *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 489 F. 2d 1247, 1249, 1251, 1254 (D.C. Cir. 1973). In so doing the Court rejected industry argument that:

> * * * the Administrator's findings are insufficient in that they are based to a large extent on data which does not directly and specifically relate to the use of DDT to combat the boll weevil and the bollworm in the cotton growing areas of the Southeast.

The court went on to find that:

> It is true that much of the evidence in the record concerning dangers of DDT does not specifically relate to this one area or to the use on cotton crops. However, it is not necessary to have evidence on such a specific use or area in order to be able to conclude on the basis of substantial evidence that the use of DDT in general is hazardous. The Administrator has pointed to evidence in the record showing that use of DDT except in minuscule amounts in highly controlled circumstances should be curtailed because of unreasonable risks to health and the environment. Reliance on general data, consideration of laboratory experiments on animals, etc., provide a sufficient basis to support the Administrator's findings, even with regard to each special use of DDT. 489 F. 2d at 1253–54 (footnotes omitted).

B. The Required Procedures. In cancellation and suspension cases where EPA has finally determined to cancel or suspend a pesticide registration after exhaustive notice and opportunities for hearing as mandated by FIFRA and the APA, fairness requires that such final orders not be modified or reversed lightly.[4] Such prior orders should not be modified or reversed without notice and opportunity for formal public hearings. The formal on-the-record decision making process imposed by FIFRA and the APA as a necessary prerequisite to final cancellation or suspension would be rendered meaningless if the Administrator were to modify or reverse such orders without notice to the public, without an opportunity for formal hearings and without limiting his consideration to a formal hearing record. Such an informal process could greatly prejudice the interests of parties to the original proceedings. In the original proceedings they had the opportunity to be represented by counsel, to present witnesses and to cross-examine witnesses of other parties. They had the opportunity to argue their cases before an independent hearing examiner and before the Administrator. An informal process which modified or reversed a final order would not provide such opportunities, would not protect the procedural rights of affected persons and would undercut the statutory scheme required by FIFRA. As the Court concluded in DDT II, "when Congress creates a procedure that gives the public a role in deciding important questions of public policy, that procedure may not lightly be sidestepped by administrators." 439 F. 2d at 594.

Formal reconsideration of prior orders should only be granted, however, where there is substantial new evidence which may materially affect the order. The provisions of FIFRA relating to notice and to the opportunity of adversely affected parties to join in formal hearings are broadly drafted to permit maximum participation in the cancellation proceedings by other Federal agencies, the States, industry, environmental groups, and private citizens. As the Court noted in *DDT II*, "the statutory scheme contemplates that [pesticide cancellation] questions will be explored in the full light of a public hearing. * * *" 439 F. 2d at 594. With such broad opportunities to participate in the original proceedings, the public interest—and the interests of the parties who participated in such proceedings—requires that the issues before the Administrator not be relitigated without a threshold determination that there is substantial new evidence which may maerially affect the prior order. This procedure does not prejudice the interests of parties seeking modification. If there is substantial new evidence, which may materially affect the prior order, a formal hearing should be convened to adjudicate whether such evidence requires modification or reversal of the prior order. On the other hand, however, the public interest demands that public agencies not be required to expend limited resources on reconsideration of facts previously adjudicated. Public resources should not be committed to reconsider a prior final order unless there is substantial new evidence which may materially affect such order.

For the foregoing reasons, EPA has adopted Subpart D to the Rules of Practice (40 CFR Part 164) setting forth the procedures to be followed in the case of an application under FIFRA sections 3 or 18 which requests use of a pesticide at a site and on a pest for which registration has been finally cancelled or suspended. These revised procedures require that in any such case the Administrator will initially determine, on the basis of the application and supporting data, whether there is substantial new evidence which may materially affect the prior order and whether such evidence could not have been discovered by due diligence on the part of the parties to the original proceeding. In any case where it is determined, as in this case, that there is no substantial new evidence which may materially affect the prior order, then the application will be denied.

In any case where it is determined that there is such evidence, then a formal hearing will be convened to determine whether such evidence materially affects the prior order and requires its modification. In such a case, the ultimate determination will be made on the basis of the record in the adjudicatory hearing and the recommendations of the administrative law judge presiding over the hearing, taking into account the human and environmental risks found by the Administrator in his prior order and the cumulative impact of past, present, and anticipated uses in the future.

The procedures also provide that in emergency circumstances the Administrator may rule on the application without convening a formal hearing when he determines that: (1) The application presents a situation involving need to use the pesticide to prevent an unacceptable risk to (i) human health, or (ii) fish and wildlife when such use would not pose a human health hazard; and (2) there is no other feasible alternative solution to such risk; and (3) the time available to avert the risk to human health or fish and wildlife is insufficient to permit convening a hearing; and (4) the public interest requires the granting of the requested use as soon as possible.

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[4] In addition to DDT, in each of the other major cancellation and suspension proceedings initiated pursuant to FIFRA Section 6, EPA has similarly provided extensive notice and formal hearing opportunities.

The aldrin and dieldrin suspension order issued by the Administrator on October 1, 1974, followed almost three years of administrative proceedings. The initial cancellation notice for the major uses of aldrin and dieldrin was issued by the Administrator on March 18, 1971. Formal administrative hearings commenced on August 7, 1973. During the following twelve months of hearing, 249 witnesses testified, and over 35,000 pages of transcript and exhibits were considered and the suspension is now before the Court of Appeals for the District of Columbia.

Similarly, the two administrative proceedings currently in progress with respect to pesticide products containing mercury and mirex have involved lengthy hearings. The notice of intent to hold hearings on mirex was issued on March 28, 1973. The formal hearings were begun on December 3, 1973, and have not yet concluded. To date, over 60 witnesses have testified in those hearings resulting in a record of over 12,400 pages. As in the aldrin and dieldrin proceedings, a scientific advisory committee report on mirex was prepared prior to the commencement of the formal hearings.

The cancellation of pesticide products containing mercury was issued on March 22, 1972. The formal administrative hearings began on October 1, 1974, and are still in progress. Forty witnesses have testified thus far in those hearings generating a record of over 2,400 pages.

This provision for dispensing with a formal hearing does not apply to the Louisiana application since the use of DDT on cotton does not involve a need to use the pesticide to prevent an unacceptable risk relating to human health or fish and wildlife.

In the case of the petition by the State of Louisiana, notice of these revised procedures and of a tentative time schedule within which they would operate was given to all parties involved in the informal public hearings held in Washington, D.C., on March 5, 1975. Because of the March 5, 1975 notice to interested parties, including the State of Louisiana, formal adoption of such procedures on the eve of my decision as to substantial new evidence did not prejudice the interests of interested parties including the State of Louisiana. All such parties received notice of these procedures on March 5 and were encouraged to submit an additional brief statement summarizing what they maintained to be substantial new evidence on March 10, 1975. The State of Louisiana, and other interested parties have submitted such statements.

In addition, the Louisiana application was filed under FIFRA section 18 pursuant to which Louisiana is required to show that there is a pest outbreak for which no alternatives are available and which will result in significant economic or health problems. 40 CFR Part 166. Louisiana has questioned whether EPA is now changing the substantive standard by which its application will be evaluated. The procedures adopted do not, however, change the substantive rules by which the Louisiana application will be measured. The issues raised by the Louisiana application under section 18 were adjudicated and finally decided in the 1972 DDT cancellation case. In that case the Aministrator was required to make, and made, specific findings and conclusions with respect to the risks and benefits associated with DDT use on cotton. The Administrator's findings and conclusions were then affirmed by the Court of Appeals for the District of Columbia in *DDT V*. Thus, no showing under section 18 of a pest outbreak, of unavailability of alternatives and of significant economic problems could now be made without substantial new evidence. The procedures adopted clarify the application of the general rules under sections 3 and 18 to specific cases, such as the Louisiana application, which in substance request modification or reversal of a prior final order.

These procedures are not inconsistent with previous EPA practice. Since the 1972 Order, EPA has received approximately 44 applications under FIFRA sections 3 and 18 for the use of DDT on cotton. All of these applications have been denied summarily on the basis that they failed to set forth sufficient new information which would warrant approval in view of the general human and environmental risks associated with such DDT use and enumerated in the 1972 Order.

In addition to the 44 DDT-cotton requests, EPA has received applications for uses of DDT on other crops which were not at issue in the prior DDT adjudicatory hearings. In 1973 and 1974 DDT was authorized for use under FIFRA section 3 for the pea leaf weevil in Idaho and Washington. These authorizations considered the available evidence "in light of the terms of the June 1972 [cancellation] order * * *." 39 FR at 10322. However, the use of DDT for the pea leaf weevil was not cancelled by the Administrator in his 1972 Order and thus the pea leaf weevil applications did not in substance request the use of a pesticide on a site and against a pest which was cancelled by final order. In fact, the pea leaf weevil was first detected at damaging levels in 1970 and relatively little was known about the impact of climatic and biotic factors on its development or about resistant crop strains or planting techniques which could mitigate infestation. The area of application was very dry (15–20 inches of rain per year), had few trees and little vegetation other than the dry pea crop. The area involved thus presented little potential for contamination of aquatic ecosystems. Because the weevil was a new pest, there were no pesticides registered for the requested use to protect dry peas in Idaho and Washington which accounted for 95 percent of total U.S. dry pea production.

In 1974 DDT was authorized for use by the U.S. Forest Service on the Douglas-fir tussock moth in parts of Oregon, Idaho and Washington. That decision specifically stated that: "The use of DDT for control of the tussock moth was not specifically addressed in [the 1972 DDT cancellation] order, but there is no present registration of DDT for this purpose." 39 FR 8377. The use of DDT on the Douglas-fir tussock moth had been registered in 1947 by the Forest Service, but the use was later abandoned by USDA in 1969. Accordingly, the use of DDT to control the Douglas-fir tussock moth had not been subjected to formal review through an adjudicatory proceeding. In addition, the tussock moth case presented a significant environmental need for DDT. At stake were 650,000 acres of mature forests containing the Douglas-fir. In 1972 and 1973, the moth had defoliated trees on 800,000 acres—of which 17,000 acres of forest were completely killed and on an additional 71,000 acres at least half of the Douglas-fir were killed. Mature forests—including Douglas-fir—require many years to develop even assuming prompt and thorough replanting. A new "crop" cannot be grown "next year." Moreover, the defoliation of such vast forest lands presented serious fire hazards. It was estimated that with any fire outbreak a forest defoliated by the tussock moth would burn and spread 6 times faster than normal (25 acres per hour rather than 4 acres per hour). Thus, anticipated defoliation presented serious health hazards as well as economic losses (estimated $67 million loss). In addition, even without forest fires, extensive defoliation of watershed areas may have caused significant water pollution by virtue of sedimentation attributable to runoff. Finally, the Douglas-fir tussock moth application sought the use of approximately 490,000 pounds of DDT over 650,000 acres, whereas the Louisiana application is for 2,250,000 pounds over 450,000 acres—roughly 5 times more DDT per acre.

Although the status of DDT requests, such as those for cotton, as petitions for reconsideration of the 1972 Order and the standard for determining whether to reconsider the 1972 Order (substantial new evidence which may materially affect the prior order) may not have been fully articulated in determinations issued by EPA since the 1972 Order, in substance EPA was applying the same standards which have been formally adopted for this case and for similar cases in the future. To the extent that prior practices and procedures may have differed from the recently promulgated procedures, such changes are necessitated for the reasons set forth in this opinion and in the preamble to Subpart D of the Rules of Practice.

C. Hearings on the Louisiana Application. The five days of informal public hearings already held in connection with the Louisiana application produced 1180 pages of transcript and numerous exhibits. A seven-man panel of EPA technical and administrative experts heard the testimony presented, reviewed exhibits submitted by the participants, and analyzed the statements submitted by all interested parties which summarized the evidence bearing on the Louisiana petition. This panel was also charged to review the whole of the data and make a preliminary assessment as to whether "(1) the applicant has presented substantial new evidence which may materially affect the prior cancellation or suspension order and which was not available to the Administrator at the time he made his final cancellation or suspension determination and (2) such evidence could not, through the exercise of due diligence, have been discovered by the parties to the cancellation or suspension proceeding prior to the issuance of the final order." (40 CFR 164.132 (a)).

The report and conclusions of the panel were presented to me on Thursday, March 13, 1975. The panel concluded that Louisiana had not presented any substantial new evidence which may materially affect the 1972 Order. The report and conclusions of the panel are being published as an appendix to this Statement.

Having reviewed and discussed the report and conclusions of the panel I have made a separate evaluation of the factors involved in the Louisiana situation including consultation with the EPA staff and review of the summary statements filed by the parties to the informal hearings. In addition, I have informally consulted with a panel of the EPA Hazardous Materials Advisory Committee (HMAC). The HMAC panel was charged to explore preliminarily scientific questions which may have been presented. The HMAC panel spent Friday, March 14, reviewing the Louisiana application and discussing the questions presented with the EPA hearing panel and others. The HMAC panel did not reach any conclusions or make any recommendations with respect to whether there was any substantial new evidence which may materially affect the 1972 Order. I appreciate the HMAC panel's conscientious efforts and in reaching my decision I have taken into account my brief discussions with them.

III. Hazards From The Requested Use of DDT. Very little evidence concerning human health and the environment was actually presented by Louisiana during the informal proceedings. Certainly there is no evidence before me that would mitigate the clear findings of Administrator Ruckelshaus in 1972 with respect to environmental harm and risk to man posed by DDT. In fact, data produced since the 1972 hearings that have been called to my attention reaffirm and augment the serious nature of the environmental and human health hazards posed by DDT.

There is no dispute that the use of 2.25 million pounds of DDT in Louisiana this year would have serious adverse environmental effects irrespective of any good faith educational or regulatory restrictions that might be imposed by either the Federal Government or the State of Louisiana. In its application (La. App. at 10), Louisiana stated that:

> It is recognized that the use of DDT, even when the precautions outlined above are taken, will result in widespread contamination of the environment with undesirable residues of this chemical.

However, Louisiana adds, without substantiation, its belief that:

> Even the most severe of the localized effects are unlikely to be of more than extremely short duration. (La. App. at 12).

I cannot agree either that the severe effects of widespread contamination and undesirable residues which result would be only local or that they would be of extremely short duration.

There are certain basic characteristics of DDT that are indisputable. These include its persistence, mobility and broad range of toxicological effects. Perhaps the most insidious of its characteristics is the fact that the most serious of DDT's toxicological effects are chronic or subchronic and most often of an irreversible nature. Such effects are not normally apparent by routine scientific observation until it is too late. This is cause for the exercise of particular vigilance and scrutiny in the evaluation of any request for the use of this compound.

The particular use in question here would in my opinion present conditions conducive to the widespread contamination and dispersal of DDT throughout the environment. There is little question but that the aerial and ground spraying of 2.25 million pounds of DDT in the August climatic conditions of Louisiana would result in considerable off-target drift and even more significant volatilization and environmental dispersion of the compounds. There is ample evidence in the 1972 record of the volatility and persistence of DDT.

One of the principal restrictions proposed by Louisiana would limit DDT application to one-half mile from dairies or forage, silage, and grain crops used to feed dairy animals. Similar type restrictions were proposed and explored in the 1972 hearings and it was concluded then that such limitations simply could not curb the environmental contamination that follows from this type of DDT use. Indeed, Administrator Ruckelshaus concluded in 1972: "I am convinced by a preponderance of the evidence that, once dispersed, DDT is an uncontrollable, durable chemical that persists in the aquatic and terrestrial environments." (1972 Order, 37 FR at 13370). Included in the 1972 General Findings were the following:

> A. No directions for use of DDT, even if followed, can over the long run completely eliminate DDT's injury to man or other vertebrate animals.
>
> B. No warning or caution for use of DDT, even if followed, can over the long run prevent injury to living man and other vertebrate animals (37 FR at 13375, VII).

Many examples of DDT's ability to persist and move in the environment were presented in the 1972 hearings. Perhaps the most dramatic example was the discovery of DDT in the wildlife of Antarctica, where of course it had never been used. This continent, with its ice shelf, lies over 600 miles from the tip of South America, over 1,000 miles from New Zealand, and over 2,000 miles from the tip of South Africa, which are the closest possible sources for its DDT contamination. From these examples, one can see the extreme unlikelihood that any of the proposed restrictions, e.g., one-half mile aerial application restriction around dairy farms, etc., will mitigate the resulting DDT contamination of food, feed, air and human water supplies as well as fish and wildlife in proximate as well as distant areas.

The significance of my initial discussion of the likely massive environmental contamination that will result from the proposed use of 2.25 million pounds of DDT centers on the resulting exposure and increased risks to humans and to wildlife. The principal risk to humans is cancer. As Judge Leventhal of the U.S. Court of Appeals for the District of Columbia pointed out, cancer is a "sensitive and fright-laden" matter compounded by the fact that carcinogenic effects are "generally cumulative and irreversible when discovered." *Environmental Defense Fund v. Environmental Protection Agency*, 465 F. 2d 528 (1972). This "sensitive" issue has been highlighted recently by the publicity given to the study showing a particularly high rate of cancer in the Louisiana area.

In 1972, then Administrator Ruckelshaus made the factual finding that "DDT is a potential human carcinogen." (37 FR at 13375, IV, A, 9). As the basis for this finding the Administrator cited the fact that: "Laboratory tests have * * * produced tumorigenic effects on mice when DDT was fed to them at high levels." (Id. at 13371). The laboratory tests referred to were cited as the Bionetics study in which mice were fed 140 ppm of DDT and the Lyons study (at that time incomplete and still in progress) in which "(i)ncreased hepatomas [liver tumors] were noted in male and female mice fed DDT at 250 ppm." (Id. at 13371 n. 20).

The Administrator further found in his evaluation of the cancer hazard of DDT that: "there is no adequate human epidemiological data on the carcinogenicity of DDT, nor is it likely that it can be obtained." (Id. at 13375, IV, A, 9(*e*)). This finding has not been challenged and remains true today. Thus, the laboratory findings of carcinogenicity retain their preeminence in the overall evaluation of the cancer risk of DDT to man. On the basis of these prior findings, I conclude that the requested use of 2.25 million pounds of DDT in Louisiana this year poses an unacceptable cancer risk to man. There is no substantial new evidence which would materially reduce the risk perceived in 1972.

Since the issuance of the 1972 Order, even more disturbing evidence of the carcinogenicity of DDT than that relied upon by Administrator Ruckelshaus has been published in the scientific literature. Nearly five months after the 1972 Order and some nine months after the close of the DDT hearing the first final report of the Lyon study, referred to as "still in progress" in the 1972 Order, was published. That report showed DDT not only to cause a significant increase in liver tumors in the first generation of mice fed 250 ppm DDT, as noted in the 1972 Order, but also revealed that a similar significant increase in liver tumors was shown in two generations of male mice fed 50 ppm, 10 ppm and 2 ppm, the lowest known dosage of DDT ever tested. *Int. J. Cancer:* 10, 489–506 (1972). The majority of the "Working Group" of an international conference of distinguished pathologists who later examined the DDT induced liver tumors from this study found the tumors to be malignant. The entire "Working Group" concluded that "exposure to DDT represents a carcinogenic risk for man." "Report of Working Group", Int. Agency for Research on Cancer, October 27, 1972.

In September of 1973, the final results of the Lyon study, extended to six full generations of mice (nearly 4,000 animals) fed DDT at 2, 10, 50 and 250 ppm levels, were published. The findings in the succeeding four generations of mice confirmed the results reported in October 1972 in the parent and first generation treatment group. In the male mice in all six generations DDT caused a significant increase in liver cancer at every treatment level including 2 ppm, the lowest dosage tested. Journal of the National Cancer Institute, Vol. 51, No. 3, September 1973.

In November 1973 a team of Russian scientists reported the results of a multigeneration DDT feeding study in which two groups of A-strain mice were fed 10 and 50 ppm DDT in the parent generation while five succeeding generations were fed 10 ppm. DDT caused a significant increase in lung tumors at both feeding levels in the parent groups. All of the five succeeding generations showed an increase in lung tumors over control animals; the increase was significant statistically in the second, third and fourth generations fed 10 ppm, the only dose so tested. *Int. J. Cancer:* 11, 688–693 (1973). This finding of DDT induced carcinogenicity at a site other than the liver supports the results of an earlier report by a Hungarian team which showed DDT to cause a progressively significant increase in leukemia and other malignant tumors at several different sites in the second through the fifth generations of mice fed approximately 3 ppm of DDT in the diet. *Fd. Cosmet. Toxicol.*, Vol. 7, 215–222 (1969).

In March 1974 the first study of the effects of the long term feeding of p,p' DDE, the principle DDT metabolite found in all humans and in the highest quantity of all of the metabolites, was reported. At the only feeding level tested (250, ppm), p,p DDE was shown to be an extremely effective liver carcinogen in both male and female mice, but particularly in females in which there was a 98 percent incidence of tumors compared to only 1 percent in the control animals. Another DDT metabolite, p,p' DDD fed at the same single feeding level caused a significant increase in lung tumors. Journal of the National Cancer Institute, Vol. 52, No. 3, March 1974.

In addition, evidence reviewed by me in September 1974 that had been introduced in the Aldrin/Dieldrin suspension hearing revealed the apparent synergistic effects on the development of tumors in mice fed DDT and Dieldrin in combination. (39 FR at 37268) While such a possibility had long been feared this was the first evidence actually demonstrating such effects. Knowing that these two compounds are stored in the tissues of the entire population of the U.S. and are and have been breathed and ingested simultaneously for years is an added cause for serious concern.

As I stated in my Order of March 14th denying the Louisiana application, these recent findings tend to reaffirm and augment the cancer hazard of DDT perceived by Administrator Ruckelshaus in 1972. Had the quantum of cancer evidence not changed since 1972 there is no doubt but that the basis for the 1972 finding of a carcinogenic risk would still lead me to concur completely with the seriousness of the cancer risk expressed in the 1972 Order. (See my October 1, 1974, Order Suspending Aldrin/Dieldrin Registrations, 39 FR 37265–72). What has been called to my attention in these informal proceedings by the National Audubon Society and others concerning more recent cancer testing does, however, convince me that the cancer hazard is not as "remote" as previously thought.

My review of the evidence in the recent Aldrin/Dieldrin suspension proceeding brought to light certain additional factors bearing on my present consideration. The apparent DDT/Dieldrin synergistic carcinogenic response discussed above is one such factor. In addition, I notice that much has been raised in the past concerning the relevance of carcinogenic results achieved in experiments using "high levels" of a compound, an issue that I was not faced with in the Aldrin/Dieldrin case. The only dosage level cited in the 1972 DDT Order as producing tumorigenic results was 250 ppm, although reference was made to a second study in which it is known that 140 ppm was the feeding level used. We now have evidence that DDT is capable of causing a significant incidence of tumors in test animals at levels as low as 2 ppm in the diet, the lowest dosage ever tested.

For purposes of reference, it should be noted that in 1972, the most recent year for which complete figures are available, DDT residues were found in the tissues of 99.93 percent of some 4,285 humans involved in the annual EPA Human Monitoring Program. The *average* level in these humans was 11.15 ppm DDT or nearly five times higher than the daily intake shown to cause a significant incidence of tumors in mice. The maximum level of DDT found in any one individual was 311.34 ppm. This recent information was introduced in the Aldrin/Dieldrin suspension hearing and is an update of the human monitoring data considered in the 1972 DDT hearing which reported similar findings.

Data from the Human Monitoring Program reveal that DDT quantitative residue values in humans are not uniformly distributed throughout the population. Residents of the South have consistently shown higher levels of DDT in their tissues than residents of other parts of the country. Moreover, black males, one of the highest cancer risk segments of the population, store the highest amounts of DDT.

I realize that a valid direct quantitative comparison between intake levels causing cancer in test animals and storage levels in humans is not possible at this time. Among others, one complicating factor is that there are some chemical agents to which man is more sensitive than test animals and some agents to which man is less sensitive. We have no way of knowing or predicting outside of actual measurable human experience. I cite these values for several important reasons, however. First, since storage is a function of intake, these levels demonstrate a continuous human exposure to DDT from past usage. Second, the fact that humans are storing such significant levels in comparison with dosage levels in the same range which can produce irreversible carcinogenic effects is a sobering and extremely cautionary observation. Third, our experts tell us that because of the persistence of DDT these levels in humans based on 1972 data, are not expected to decline significantly over the next several years. Thus, any consideration of a present request for further use of DDT must of necessity consider the residual effects of all past and present usage as well as any uses reasonably anticipated to occur as a result of granting the instant request for use. It is my opinion that humans in this country cannot and should not be subjected to the further DDT environmental insult that would result from a granting of the Louisiana petition.

In its summary statement of the evidence (La. Statement at 6), Louisiana cites as support for the argument that the carcinogenic risk of DDT "is now quantifiable and still remote" several statements allegedly attributable to an EPA official responsible for the reevaluation of DDT. In fairness to the official cited it should be noted that the conclusionary quote attributed to him—"Thus subsequent evidence confirms that human risk is remote and that the limited use in question poses no unreasonable risk of harm to man"—was never made and is not to be found in the reference cited. See Hearings Before the Subcommittee of the Commission on Appropriations; Subcommittee on Agriculture—Environmental and Consumer Protection Appropriations for 1975, Pt. 5, Environmental Programs, April 4, 1974.

I can find no merit in Louisiana's reliance on the sole sentence of the actual quote which mentions carcinogenicity, since it has been taken out of context and no supporting data or further explanation follow, either in the text of the Subcommittee Report or in Louisiana's evidence summary. I believe that the most complete statement of the DDT cancer evidence is found in the 1972 Order and in my discussion herein. The principles of chemical carcinogenesis which I have been guided by in my evaluation of this experimental evidence are set forth in my discussion of carcinogenicity in the Aldrin/Dieldrin Suspension Order (39 FR 37265–72).

Finally, serious concerns in connection with the Louisiana request have come both from private environmental groups, the Louisiana Wildlife and Fisheries Commission and the U.S. Department of Interior, all of whom feel that permitting the use of 2.25 million pounds of DDT would seriously jeopardize the fish and wildlife of Louisiana and surrounding areas and in particular the brown pelican, one of America's endangered species. The concern for the effects of DDT on wildlife has also been expressed by the shrimp and fishing industries of Louisiana who fear losses both through direct mortality and through seizures of shrimp and fish containing excessive DDT residues by responsible Federal authorities. Past experience has taught us that such concerns are indeed valid.

The case against DDT in 1972 was thoroughly documented in the area of environmental harm. Mr. Ruckelshaus stated in the 1972 Order (37 FR at 13371): "The case against DDT involves more, however, than a long-range hazard to man's health. The evidence presented by the Agency's Pesticides Office and the intervenors, EDF, compellingly demonstrates the adverse impact of DDT on fish and wildlife." Later in his 1972 Order (id, at 13373), Mr. Ruckelshaus reiterated this conclusion: "the Agency and EDF have established that DDT is toxic to non-target insects and animals, persistent, mobile and transferable and that it builds up in the food chain. No label directions for use can completely prevent those hazards."

I am convinced that the use of 2.25 million pounds of DDT in Louisiana this year would result in adverse impact on fish and wildlife, both in Louisiana and in surrounding areas. Since environmental hazards were covered in such detail in the 1972 Order and since no new evidence has been introduced to refute those findings I hereby incorporate by reference those appropriate discussions and findings from the 1972 Order which deal with the adverse effects of DDT on fish and wildlife.

Moreover, I am mindful of the unfortunate economic consequences that have been suffered by various food and feed industries as a result of pesticide residues in excess of established tolerances or action levels. In this particular situation the Louisiana shrimp and fish industries as well as beef cattle, dairy and animal feed producing industries are all innocent bystanders to the use of DDT on cotton. Nonetheless, they still run the real risk of suffering adverse economic consequences from resulting excessive DDT residues. The uncontrollable nature of the compound and past experience teaches us the inevitability of finding impermissible residues of DDT in certain of these food and feed commodities as a result of such massive nearby use.

IV. Need For the Requested Use of DDT. I adopt the report of the EPA seven-man review panel which is attached as an appendix to this Statement. The panel reached the following conclusions with respect to the requested use of DDT:

1. Average cotton yields have declined in the last two years as compared to the preceding ten years. However, there is no evidence to indicate that any meaningful conclusions concerning the relationship of yields to the presence or absence of DDT can be drawn from such a comparison.

2. The tobacco budworm is but one of many factors which affect yields, and it is quite clear that no evidence was presented to support the proposition that the tobacco budworm was the principal cause of reduced yields in the past two years.

3. The tobacco budworm has become a late-season cotton pest; however, it is not clear that the predominance of this pest occurred as recently as three years ago; instead, it may have risen to its present status prior to 1972. Furthermore, because of resistance problems, it is just as likely that the tobacco budworm will remain a late-season pest whether or not DDT or methyl parathion or any other currently available pesticide is used.

4. The Louisiana estimates of economic losses totally ignore the numerous factors which affect cotton yields. The underlying assumptions on which the estimates are based are inconsistent with actual experience in Louisiana and are contrary to sound analytical methodology.

5. There is no conclusive evidence to indicate whether the DDT mixture can be expected to be effective in controlling tobacco budworm in 1975.

6. Louisiana has not demonstrated that all currently registered insecticides are ineffective against tobacco budworm.

7. A repetition of cotton insecticide shortages in 1974 is unlikely to occur in 1975.

8. It is impossible to predict the likelihood of a tobacco budworm outbreak in 1973 at this time. However, if past cotton production practices are continued, and more sophisticated production methods are ignored, the likelihood of an outbreak will be enhanced.

9. Louisiana has not taken fullest possible advantages of integrated pest management techniques which other states have found to be of considerable benefit.

A. Economic Impact. The major problem which Louisiana wished to address through the use of DDT in 1975 is one of preventing additional economic loss to cotton producers who were already hard hit in 1973 and 1974. Estimates of total potential economic losses have been made by both the State and USDA. The State estimates are derived from an assumed continuation of estimated losses in 1973 and 1974; the USDA estimates from an economic model.

In its application, Louisiana estimated that tobacco budworm "specifically caused the loss of approximately 50–60 million dollars in 1974 in direct and indirect loss to the cotton industry" in the State. An economic analysis included in the State's application estimates that cotton producers' combined 1973–74 losses were $50,645,250 and that increased unit costs arising from reduced yields, i.e., unit costs of production, ginning, and warehousing, were $17,773,500. These estimates were based on the following assumptions which tend to inflate the estimated losses: (i) all losses in yields would be attributable to the unavailability of DDT, (ii) the total harvested cotton acreage was the same in both 1973 and 1974, (iii) lint cotton losses per acre were 111 pounds, and (iv) that the relative efficacy of DDT compared to alternatives, is high. This approach overlooks other factors which seriously affect cotton yields, such as, weather, planting time, disease, etc. See Report of the EPA Special Review Group (EPA Report) at 6–D.

The USDA analysis of potential economic losses was $15.8 million in 1974. Even this analysis may be subject to revision because it rests, in part, on efficacy data which the Special Review Group found to be of questionable validity. See EPA Report at 6 E/F.

No matter which estimate is taken, it must be compared to total income measures for the State to put the estimated impact into the perspective of the State's economy as a whole. Estimates of farm income and State income from 1972 show that these values were $800 million and $14 billion, respectively. Thus, while the estimated losses constitute approximately 7.5 percent of total farm income, they do not appear to represent a major upsetting factor to the total economy of the State. The potential economic effects must therefore be viewed in their proper context of localized microeconomic dislocations. This is not to say that such effects are to be dismissed lightly, since they may constitute severe burdens on individuals—farmers and ginners and their employees—and on other industries in the affected parishes. Yet, even if DDT were to achieve the results anticipated by the State, it would have the effect of alleviating cotton growers' economic problems while, at the same time, imposing certain health, environmental, and economic costs on third parties, e.g., dairy farmers, livestock producers, commercial fishermen, and so on. The estimates of potential loss discussed above include only the direct and indirect costs which might arise as a result of reduced cotton yields; there has been no allowance made for the increased costs, economic and otherwise, of using DDT as requested in the State's petition. Nor have the offsets available by improved utilization of alternative pest control techniques or alternative crops been taken into account as reductions to the estimated gross economic loss.

One of the key assumptions made in the petition is that the economic problems of Louisiana cotton growers are linked to the lack of DDT. Another is that all losses are attributable to damage by the tobacco budworm. These assumptions fall under critical analysis.

To begin with, it is necessary to examine some of the institutional factors that have affected the economic situation. An institutional change of immense importance occurred in 1974 with the introduction of the new cotton allotment program. This program was part of the 1973 Agricultural Act, and it required important changes in agricultural policies and philosophies, placing a great deal of reliance on the free market and requiring a good deal more judgment on the part of the farmer than was required under the previous programs. With respect to cotton, the Act replaced an across-the-board payment of 15 cents per pound with a target price program, i.e., when the national average price for a calendar year falls below the target price (currently 38 cents per pound), growers are reimbursed for the difference. In regard to the shift away from cotton subsidies, the Special Review Group found that cotton growers "are in a transitional period requiring adjustments not only in their production planning but also in their handling of factors which affect cotton yields and pest control, which, in many instances, are interrelated." See EPA Report at 6D.

Another important change made by the Agricultural Act was the introduction of a disaster payment program, which economically protects farmers if they lose more than one-third of their crop. In the circumstance where farmers plant cotton on non-allotment acres and suffer a large yield-per-acre loss for any season, they often are not eligible for disaster payments. This situation was relatively common in Louisiana last year, thus increasing the farmers' economic dislocation.

In the past two years, cotton price fluctuations also worked to the growers' disadvantage. In 1973, much of the cotton crop was contracted. From a market point of view, 1973 was one of the cotton

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industry's better years. But since most growers sold their crop early to futures speculators, the latter were the primary beneficiaries of rising prices during the year. At the beginning of 1974, cotton growers were particularly optimistic. Forecasts and expert thinking were oriented toward an extremely good cotton year and farmers planted large acreages, apparently relying on high price estimates. In Louisiana, acreage jumped from 530,000 in 1973 to 665,000 in 1974. A large portion of this increased acreage was planted under high risk conditions, since many farmers could not expect to be covered under the disaster payments provisions of the 1973 Act, and a good deal of cotton was planted after the optimum planting time (before May 15 in Louisiana), thereby increasing the likelihood of a late-season tobacco budworm problem. In addition, with their 1973 experience in mind, many growers chose not to contract; nationally, about 20 percent contracted in 1974, compared to 75 percent in 1973. Unfortunately, the market again worked to the growers' detriment. Toward the end of the growing season, prices fell precipitously. With costs having increased significantly, cotton growers were caught in a severe cost-price squeeze, and many of them suffered serious losses.

Naturally, the economic factors that have affected cotton production in Lousiana in recent years have also affected it in other States. Furthermore, Louisiana has not been alone in experiencing a downward trend in cotton yields in the last few years. The same thing has happened in all the Mississippi Delta cotton-producing States. In fact the USDA Crop Reporting Board's report dated January 10, 1975, shows that the other States in this region all have experienced sharper declines. According to that report, yields in 1974, compared to 1969–73 averages, declined 28–29 percent in Arkansas, Mississippi, and Tennessee; 36 percent in Missouri; and 7.5 percent in Louisiana.

In summary, 1974 was an exceedingly bad year for cotton producers in Louisiana and elsewhere—market prices were low, costs were high, and they were faced with adverse natural phenomena such as whether and insects. On the institutional side, the commodity market was incorrectly assessed.

B. Tobacco Budworm. Louisiana's application indicates that the tobacco budworm has reached outbreak proportions and has become resistant to registered insecticides.

An increase in budworm infestation has been observed in recent years, particularly during August and September when cotton is most susceptible to infestations of this pest. Resistance to insecticides, including mixtures containing DDT, has apparently played a part in the recent predominance of this pest. However, it is unclear when the predominance of the budworm in the late-season occurred. It is possible that both an increase in resistance combined with increased populations has been a developing trend which started in years when DDT was used and has continued up to the present time. The tobacco budworm may be showing resistance to all insecticides, including DDT. In any event, the data furnished to the Special Review Group have not established when the tobacco budworm outbreak occurred.

Louisiana maintained that the DDT mixture was the only effective method of controlling the tobacco budworm. The experimental testing designs used by Louisiana make it impossible to attach any significance to the claimed differences in the relative efficacy of DDT over other currently registered insecticides. In fact, some of the data submitted by Louisiana showed that one alternative pesticide had nearly the same effectiveness as the DDT-toxaphene-methyl parathion mixture, and that certain combinations of pesticides had a significant impact on cotton yields. EPA Report 6F. Accordingly, alternative controls for the tobacco budworm are available.

CONCLUSION

A great deal of consideration has been given to all aspects of the Louisiana application for the use of DDT on cotton in 1975. I have carefully reviewed the report of the EPA seven-man panel who listened to the testimony presented during the five days of informal hearings and who read all of the written exhibits submitted to the hearing record. The written summaries of the evidence submitted by interested parties have been read by me and discussed with my staff and advisors. Every opportunity has been given to the State of Louisiana to present its case in the most favorable light possible. In accordance with Subpart D of EPA's Rules and Practice for Applications Under sections 3 and 18 to modify Previous Cancellation or Suspension Orders (40 FR 12261), I have reviewed the totality of the evidence in an effort to determine whether the applicant has presented substantial new evidence which may materially affect the 1972 Order cancelling virtually all uses of DDT. The 1972 Order was an important EPA action reached after extensive administrative and judicial proceedings. The 1972 Order weighed all risks and benefits of DDT use.

I am convinced at a minimum that no substantial new evidence exists which may materially affect the 1972 Order as it relates to the cancellation of DDT registrations for cotton. Certain evidence presented, moreover, would indicate that the environmental and human risks enunciated in the 1972 Order may now be of even greater magnitude than in 1972. In addition, I find that the use of DDT on cotton in Louisiana this year is not necessary. There is no substantial evidence that DDT would be efficacious or that alternative chemical pesticides and other control techniques are unavailable or inefficacious.

Accordingly, I incorporate this statement of reasons into my Order of March 14, 1975, denying the section 18 application by the State of Louisiana for emergency use of DDT on cotton in 1975.

Dated: March 17, 1975.

RUSSELL E. TRAIN,
Administrator.

To: Acting Deputy Assistant Administrator for Pesticide Programs.
From: Special Review Group.
Subject: Louisiana's Application for Emergency Exemption.

This memorandum is the report of the special review group appointed to evaluate Louisiana's petition for an emergency exemption to use a maximum of 2.25 million pounds of DDT to control tobacco budworm on cotton this year.

1. The Issue.

The issue addressed in this report is whether:

a. The applicant has presented substantial new evidence which would justify reconsideration of the DDT cancellation order, insofar as this requested use of DDT is concerned, and which was not available at the time the cancellation order was issued, and

b. Whether such evidence could not, through the exercise of due diligence, have been discovered by the parties to the cancellation proceeding prior to the issuance of the final order.

For the purposes of this report, the determination to be made on the above issue is referred to as the determination of whether there is "substantial new evidence."

2. Background.

On June 14, 1972, after three years of intensive administrative and judicial inquiry, which included seven months of formal administrative hearings under the Administrative Procedure Act, the Administrator issued an order cancelling most DDT registrations, including all registrations for use of DDT to control cotton insects. This order was upheld by the United States Court of Appeals for the District of Columbia. At the time of the Administrator's cancellation order, the primary DDT use was for control of cotton pests and amounted to 10 million pounds annually. Thus, Louisiana's request to use 2.25 million pounds in 1975 represents approximately one fourth of the amount of DDT used on cotton at the time of the cancellation order.

Last year, EPA allowed two uses of DDT, i.e., 500,000 pounds to control tussock moth and 10,000 pounds to control the pea leaf weevil. Unlike the use of DDT to control cotton insects, which was a registered use until the cancellation and which was a major issue in the cancellation proceedings, its use to control tussock moth and pea leaf weevil was not registered at the time of the cancellation and was not considered in the cancellation proceedings.

3. Louisiana's application.

Louisiana is requesting an emergency exemption for the use of 2.25 million pounds of DDT in combination with toxaphene and methyl parathion to control a possible tobacco budworm infestation. There would be up to five applications of the DDT mixture at five-day intervals. On a per acre basis, each application would consist of one pound of DDT plus two pounds of toxaphene and one-fourth to one-half pound of methyl parathion. DDT would be applied only when there is a tobacco budworm infestation at or above levels at which economic injury would be expected to occur. Use of the DDT mixture would not begin until August 1975. Farmers would be urged to take certain measures to minimize use of DDT and minimize its environmental impact, but for the most part these measures would not be mandatory.

4. EPA Actions.

Louisiana's petition was delivered to EPA on January 24, 1975. A notice of the receipt of the petition was published February 18, 1975, along with a notice of public hearing to be held on February 27–28 in Baton Rouge and March 3 in Washington, D.C. The hearings in Washington were extended to the 4th and 5th of March upon notice given in Baton Rouge. Extensive testimony was presented by representatives of farm environmental groups and Federal agencies and by various experts and individual citizens. These hearings were conducted by the special review group for the purpose of gathering information to evaluate Louisiana's petition.

5. Analytical Framework.

For purposes of evaluating Louisiana's application, the major representations were identified and broken down into the following major premises in order to understand the underlying assumptions on which the representations were based:

A. Cotton yields have declined by an average of 121 pounds per acre in the last two years as compared to the preceding ten.

B. Failure to control tobacco budworm has been the principal cause of the reduced yields in the past two years.

C. The tobacco budworm problem has reached outbreak proportions in the last three years and has become the major late-season cotton pest.

D. The reduced yields in the last two years have had a serious economic impact.

E. The mixture of DDT-toxaphene-methyl parathion was effective against the tobacco budworm when it was last used and can be expected to be effective this year.

F. Currently registered insecticides are ineffective against heavy infestations of tobacco budworm.

G. There will be a shortage of currently registered insecticides.

H. It is anticipated that tobacco budworm will be a major problem again in 1975 and will significantly reduce cotton yields.

I. The requested use of DDT poses no unreasonable risk to human health.

J. Cotton growers will use DDT in accordance with a program designed to control its use and minimize environmental impact.

K. Integrated pest management techniques are useful but will not replace chemical control when outbreaks occur.

6. Analysis.

A. Cotton yields have declined by an average of 121 pounds per acre in the last two years as compared to the preceding ten.

B. Failure to control tobacco budworm has been the principal cause of the reduced yields in the past two years.

These statements represent a narrow view of what has been happening in Louisiana's cotton-producing industry. They overlook significant data about cotton production in Louisiana in recent years and important factors affecting cotton yields.

Louisiana's yield data are presented in Attachment A, which is a reproduction of a table included in the State's application. For convenience, the State's graphic presentation of the same data is reproduced as Attachment B.

There is a serious question as to whether the comparison of 1963–72 average yields with 1973–74 results puts the data into meaningful perspective. In testimony at the public hearings on Louisiana's application, other ways of parsing the data were suggested. For example, it was suggested that the year-to-year reductions during the past two years be compared with the average annual decline from 1966 through 1972, on the ground that the latter period runs from the year in which the first indication of tobacco budworm resistance to insecticides occurred in Louisiana through the last year in which DDT was widely used.

A meaningful comparison would reflect, or otherwise take into account, all the variables that could affect cotton yields. Louisiana has not made such a comparison. Instead, the State has argued that weather changes account for year-to-year fluctuations in cotton yields but that man-made factors are responsible for long-term trends, and has asserted that withdrawal of DDT is the only significant man-made change that has occurred in recent years.

In Louisiana, there has been a downward trend in cotton yields extending back to 1968. Dr. John S. Roussel, Coordinator of Cotton Research, testified: "From 1968 through 1974, annual fluctuations can again be noted but now the trend is downward." In the first four years of this period (indeed, throughout the 1963–72 period), DDT was available and was widely used in combination with toxaphene and methyl parathion. Yet, yield losses were 85 pounds in 1967 and 67 pounds in 1972; both figures are larger than the year-to-year reductions in the last two years.

A multitude of factors—many of which are interrelated—affect cotton yields. They include weather conditions, e.g., amount and timing of rainfall; occurrence of drought; soil type; plant variety used, e.g., whether it is early or late maturing, insect or disease resistant, and so on; time of planting; planting pattern in the field; occurrence of disease, e.g., boll rot; timing and magnitude of insect infestations; quantities of fertilizer and herbicides applied to the crop; use of pesticides; existence of insect resistance to pesticides, etc.

To illustrate the effect of some of the interrelationships on cotton yields: Late planting may mean that the cotton will still be growing late in the season when tobacco budworm population levels are most likely to be high. Heavy rainfall late in the Summer also extends the growing period and makes the cotton plant more vulnerable to tobacco budworm infestations.

Louisiana's application concedes that the interrelationship of tobacco budworm and other factors contributed to the recent yield reductions (even though the Governor's transmittal letter attributes all losses to the tobacco budworm). Late planting and weather conditions were cited in the application as causes for yield reductions.

A more detailed analysis was provided by Dr. L. D. Newsom, Head of the Entomology Department at Louisiana State University in his response to a USDA questionnaire in November 1974. The following is an excerpt of Dr. Newsom's letter regarding the 1974 crop:

"Damage from *Heliothis* infestations ranged from none to light on cotton that was planted during the proper period, grew off normally, was not subjected to drought stress, matured normally, and was treated properly. It was moderate to a total loss where the crop was planted late. Moderate to severe losses occurred where cotton was subjected to drought stress during July and the first part of August followed by rain and regrowth during the latter part of the season. In these situations, satisfactory control of the tobacco budworm was not obtained with any treatment regimen.

"Better data will be available on losses upon completion of a survey that is in progress. It should be strongly emphasized that relatively cool, cloudy conditions with excessive rain during late August and September resulted in poor growing conditions for maturing the crop and one of the most (word not legible on xerox copy) outbreaks of boll rot on record in Louisiana. Many growers have attributed all of their losses, regardless of cause, to *Heliothis* damage."

In the recent hearings, Dr. Newsom was asked for an estimate of the extent to which yield losses could be attributed to tobacco budworm. He responded that he would place it at more than 50 percent and less than 100 percent.

On the same question, Dr. John S. Roussel, coordinator of cotton research in Louisiana, testified that he could not "partition this yield reduction in detail" and went on to say:

> The best we can do is assume that over a ten-year period we have had all of these factors involved. Admittedly, two years is not an awful lot to compare ten years to. but this is the best data we have at the present time. And we know that the population was there. We know that it was in existence and it was not being controlled.

Louisiana's assessment of the situation also fails to take into account various other factors that could have influenced yields during the 1968–74 period. There was a trend toward later harvesting of the cotton crop. Dr. Roussel's testimony showed that the percentage of cotton harvested in October-November increased from 64 percent in 1963–65 to 85 percent in 1972–74. Later harvesting is relevant because it prolongs the exposure of the cotton crop to late-season pest infestations. There also was an upward trend in acreage planted; the average annual increase was 40,000 acres. USDA's report on Louisiana's application indicates that "as acreage in a parish increases, yield per acre decreases as poorer quality land is utilized."

C. The tobacco budworm has reached outbreak proportions in the last three years and has become the major late-season cotton pest.

Louisiana officials have asserted that there has been a marked change in the seasonal pattern of tobacco budworm infestations. There generally are two periods of *Heliothis* infestation in cotton; the first one occurs during June and early July, while the second begins the following month and continues until the crop matures, when it is no longer vulnerable to attack by the tobacco budworm. Historically, tobacco budworm has been the predominant insect during the early infestation (which is less serious because the cotton plant is still capable of compensating for insect damage), while bollworm has been predominant later in the season. According to Louisiana's data, a shift has occurred, in that tobacco budworm is now predominant during the later infestation. This shift is suggested by the following table, which is a reproduction of one appearing in Louisiana's application; however, the absence of data for the period 1965–1971 does not permit any inferences to be drawn as to precisely when the alleged shift occurred:

Percentages of Heliothis collected from cotton that were identified as tobacco budworm

Month	Year					
	1962	1963	1964	1972	1973	1974
July†	66	12	6	......	34	25
August	5	2	1	74	22	56
September	36	9	3	85	91	86

The increased level of late-season tobacco budworm apparently is related to the increase in tobacco budworm resistance to insecticidal control. This theory has been propounded by Dr. Graves, Louisiana State University, with respect to tobacco budworm resistance to organophosphorous compounds. It is supported by data reported by Hanna (1973, A Quarter-Century of Cotton Insects in the Brazos Valley). In analyzing the shift in tobacco budworm population levels in the

Brazos Valley (Texas) between 1962–72, Hanna stated that at the beginning of this period, tobacco budworms were highly resistant to chlorinated hydrocarbons but could be controlled with high doses of organophosphorous insecticides. At this time bollworms had not developed any massive resistance. At the end of the period tobacco budworms had developed resistance to organophosphates also; the bollworms were resistant to chlorinated hydrocarbons but not to organophosphorous materials. For the last three years, considerable budworm problems have occurred in late-maturing fields.

It is emphasized that pesticide resistance in the tobacco budworm in Texas developed first to organochlorine insecticides (DDT-toxaphene) and then to organophosphorous insecticides (primarily methyl parathion). Louisiana's data do not show exactly when the shift in tobacco budworm infestations occurred, but resistance to DDT-toxaphene in Louisiana was noted by Dr. Graves in 1966. Dr. Roussel stated that in the decade 1963–72 the combination of DDT-toxaphene-methyl parathion was applied an average of 10 times per acre per season on cotton grown in Louisiana. Obviously, at this rate of use, the selection pressure for development of resistance by tobacco budworm to the DDT mixture was intense. Dr. Graves' resistance data, as submitted in the State's petition, shows that of the 12 sites where insecticide resistance was detected in 1972–74 sampling, seven had relatively high levels of resistance to DDT-toxaphene. Thus, the contention that the tobacco budworm population shift has been very recent (after 1972) and due primarily to resistance to organophosphorous compounds is not entirely supported by data, though it could possibly be true.

In contrast, Dr. Pimentel, Cornell University, has noted in his testimony on the tobacco budworm problem in Louisiana that "from 1967 through 1972, when DDT was removed, you will note there is an average decline in yield per acre of cotton of about 30 pounds * * * Now, if you take the reduction from 1972 to 1973, we have a reduction of 28 pounds. And then the reduction from 1973 to 1974 is a reduction of 32 pounds. So that the average reduction in yield for those last two years is exactly equal or similar to the reductions in yield that you had the previous * * * 6 or 7 years. So that I say the trend here as being I would agree with my colleagues that there is a decline in yield, and I would agree with Dr. Newsom that this is probably a good deal due to resistance of the budworm, if we can go by the experience that occurred in Mexico and Texas, that this resistance is increasing and there is a decrease in yield, but that this reduction in yield has not increased following the removal of DDT, it has only remained constant because the insects are becoming more and more resistant to all of the insecticides used." It should be noted that more recent 1974 data, which had not been brought to Dr. Pimentel's attention, indicate that the 1973–1974 yield reduction was 51 pounds. The additional reduction may be due to increasing tobacco budworm resistance to all insecticides and/or to the other factors that may have affected 1974 yields (see 7B).

D. The reduced yields in the last two years have had a serious economic impact.

In his letter transmitting Louisiana's application, Governor Edwards estimated that tobacco budworm "specifically caused the loss of approximately 50–60 million dollars in 1974 in direct and indirect loss to the cotton industry" in Louisiana. An economic analysis in the State's application estimates that cotton producers' combined 1973–74 losses were $50,645,250 and that increased unit costs arising from reduced yields, i.e., unit costs of production, ginning, and warehousing, were $17,773,500.

The $50,645,250 figure is an upper estimate based on five assumptions, one of which is a lint cotton price of 60¢ per pound. Historically, the highest price paid to cotton producers has been 58.4¢ per pound. In 1973, the average price was 37.5¢ per pound. In 1974, the average price was 46.3¢ per pound.

Four other assumptions underlie the $50 million figure:

That 615,000 acres were harvested. This figure approximates the 1974 harvest. The 1973 total was 520,000 acres.

That lint cotton loss per acre was 111 pounds. This figure is the difference between 1963–72 average yields and 1973–74 average yield; see Attachment A. Also see 6 A/B for comments on the validity of this time-series comparison.

That all yield losses in 1973–74 were due to the unavailability of DDT. Other factors affecting cotton yields are ignored. See 6 A/B for a detailed analysis of this assumption.

That use of DDT-toxaphene-methyl parathion would have resulted in yields closer to the 1963–72 average, or, in other words, that the relative efficacy of the DDT mixture would have been high, compared to the best alternative. See 6 E/F for analysis of this assumption.

These assumptions are inconsistent with actual experience in Louisiana, unsupported by experimental testing of cotton insecticides, and/or contrary to sound analytical methodology. Each assumption tends to inflate the dollar value of the economic impact on cotton producers.

In an attempt to predict the economic impact of not using the DDT mixture this year, a consultant to USDA has employed a model that takes into account a number of factors that affect cotton yields, including amount and timing of rainfall, cotton acreage, bollworm infestation, and boll rot. It was assumed that use of the DDT mixture would save two insecticide applications per acre and, in accordance with the State's controlled use program, involve $3 per acre for scouting and supervision costs. The resulting estimate of the cost of not using the DDT mixture is about $15.8 million. The methodology used here is much sounder and more sophisticated than that employed by Louisiana in estimating 1973–74 losses. Though there has not been time to examine the USDA model in detail, it should be noted that the assumptions as to relative efficacy of the DDT mixture and alternatives are based on the testing performed in Louisiana in recent years and therefore must be considered in light of the analysis presented in 6 E/F.

There is no question that some notable changes have occurred in the economics of cotton production over the past few years. Starting in 1974, cotton growers no longer received from USDA a subsidy for cotton produced on their allotted acreage. Previously, they received 15¢ per pound subsidy. In the DDT cancellation order, the Administrator noted that there was testimony that "this subsidy is the difference between profit and break-even (but that) it is not clear whether or not break-even includes a return to the farm owner in terms of salary or return on his investment." The legislation repealing this subsidy was enacted in 1973.

The legislation now in effect provides for Federal payments to cotton growers of an amount equal to the difference between the national average market price during a calendar year and a so-called target price. In 1974, the first year in which this new policy was in effect, cotton prices declined sharply late in the year; nevertheless, because the calendar-year average was above the target price (38¢ per pound), cotton growers received no payments. Legislation now under consideration in the Congress would raise the target price to 48¢ per pound.

As long as subsidy payments were being made, cotton growers had a cushion that protected them, to some extent, from the impact of price and production-cost variations and yield fluctuations. With their allotment acreage subsidized, they had an incentive to try to maximize yields by using large quantities of fertilizer and chemicals and planting indeterminate or late-season cotton varieties, even though such practices might, in the long run, contribute to the occurrence of pest problems. Nevertheless, yields in Louisiana began decreasing after 1968, and growers planted increasing acreage to maintain their incomes. USDA's report notes that increasing acreage is associated with declining yields; see 6 A/B. Without the subsidy program, cotton growers are forced to rely on their own estimate of future cotton supply and demand in making their production decisions. Thus, from an economic standpoint, they are in a transitional period requiring adjustments not only in their production planning but also in their handling of factors which affect cotton yields and pest control, which, in many instances, are interrelated.

There was testimony during the DDT cancellation hearings to the effect that demand for cotton was strong and stocks were low. In 1973, cotton prices, which had been stable for many years, began rising. They reached an all-time peak of 58.4¢ per pound in April 1974. With cotton prices so high, cotton growers substantially increased their acreage. In Louisiana, acreage planted jumped from 530,000 in 1973 to 665,000 in 1974. Then, prior to harvest, cotton prices dropped sharply. At the same time, production costs were increasing. Various data on production costs were cited at the public hearings on Louisiana's application, but no comprehensive figures were presented. There also was testimony that Louisiana cotton growers are having difficulty obtaining loans to cover production costs; again, no comprehensive data were presented.

Naturally, the economic factors that have affected cotton production in Louisiana in recent years have also affected it in other States. Furthermore, Louisiana has not been alone in experiencing a downward trend in cotton yields in the last few years. The same thing has happened in all the Mississippi Delta cotton-producing States. In fact, the USDA Crop Reporting Board's report dated January 10, 1975, shows that the other States in this region all have experienced sharper declines, ranging from 28–29 percent in Arkansas, Mississippi, and Tennessee to 36 percent in Missouri.

Whether substantial new evidence has been presented in the economics area is a difficult question. The difficulty lies largely in determining the materiality of evidence concerning economic changes experienced by cotton growers in one of several States where such changes have occurred. It is clear that the DDT cancellation order dealt with the cotton economy as a whole. No assumptions were made that cotton-production costs and profits in specific areas, such as Louisiana, were the same as those in other cotton-producing areas or that relative cotton-production costs and profits in the various cotton-producing areas would remain static in the future.

The economic outlook for any single area obviously was not the touchstone of the Administrator's statement that: "I am convinced by the evidence that continued use of DDT is not necessary to insure an adequate supply of cotton at reasonable cost." The evidence presented by the State of Louisiana, which has accounted for about five percent of the Nation's total cotton production in recent years, clearly does not indicate that an adequate supply of cotton will not be available if Louisiana cotton producers are barred from using DDT.

There is evidence that the cost of using (the DDT mixture will be lower than the cost of using) alternatives, such as toxaphene-methyl parathion or EPN-methyl parathion. Taking into account both material and application costs and assuming that use of the DDT mixture will save two applications per acre during the period of treatment for tobacco budworm, it is estimated that the cost differential would range from eight to twelve dollars per acre; this figure must be reduced by three dollars per acre (USDA estimate) to cover the costs of the field scouting and supervision contemplated by Louisiana's program for controlling the use of the DDT mixture.

Of paramount importance, however, is the lack of sound evidence on which to base any prediction as to the relative efficacy of the DDT mixture and alternatives in 1975. In short, any economic benefits attributed to the use of DDT are, at best, speculative at this time. Even were such evidence available, it would not demonstrate that an adequate supply of cotton could not be produced at a reasonable cost, either in Louisiana or elsewhere. In this connection, it should be noted that while other States responding to a USDA survey in November 1974 noted the existence of some difficulty in controlling tobacco budworm infestations, including insecticide resistance problems, none of them suggested that use of the DDT mixture would be necessary this year.

E. The mixture of DDT-toxaphene-methyl parathion was effective against the tobacco budworm when it was last used and can be expected to be effective this year.

F. Currently registered insecticides are ineffective against heavy infestations of tobacco budworm.

In the DDT cancellation order, the Administrator's factual findings as to the benefits of DDT included the following:

That DDT is useful for the control of certain cotton insect pests.

That cotton pests are becoming resistant to DDT.

That methyl parathion and other organophosphate chemicals are effective for the control of cotton pests.

Efficacy

The Administrator's order cancelling DDT registrations suggests that other registered pesticides were considered to be at least as effective as the DDT mixture; in contrast, Louisiana's application asserts that the DDT mixture is the only one considered effective against heavy infestations of tobacco budworm.

A detailed analysis of Louisiana's data is presented in Attachment D to this report. Very briefly, this analysis indicates that deficiencies in the experimental design of the testing performed at State experiments stations and gaps in the data gathered during this testing make it impossible to draw any clear-cut conclusions as to the relative efficacy of the DDT mixture and other insecticides. The data derived from testing in 1972 (the last year in which the DDT mixture was tested) do not demonstrate that alternatives to the DDT mixture were ineffective; indeed, when yields in treated vs. untreated plots are compared, at least one of the alternatives, i.e. chlordimeform, appeared to be nearly as effective as the DDT mixture. Looking at all 1972–74 test results, it is apparent that several alternatives produced yields which were significantly greater than yields in untreated plots. These alternatives included methyl parathion used alone and in combination with toxaphene, EPN, and chlordimeform; a combination of toxaphene, methyl parathion, and methomyl; and a chlordimeform-methomyl combination.

Another significant gap in Louisiana's presentation is the absence of data on the extent and duration of tobacco budworm infestations at or above the economic injury threshold level. This point is germane to the issue of whether five applications of the DDT mixture at five-day intervals, as proposed by Louisiana, would effectively control tobacco budworm. Louisiana's data on the efficacy of the DDT mixture were based on nine applications in one test and eleven applications in the other.

USDA's support of the statement that no currently registered alternatives to the DDT mixture will effectively control tobacco budworm is based on Louisiana's 1972 test data (the deficiencies of which are briefly described above and delineated in greater detail in Attachment C) and on USDA testing at Waco, Texas, in 1972. The Waco test was merely a comparison of the DDT mixture and no treatment; it had no bearing on the relative efficacy of the DDT mixture and alternative materials.

Pesticide Resistance

Louisiana officials interpret their data on pesticide resistance as showing that resistance to pesticides other than the DDT mixture occurs in all the major cotton growing areas in the State. In 1972, however, studies of pesticide resistance included tobacco budworm samples from one site in District III and none in Districts II, IV, VI, and VII; together these districts accounted for 74 percent of the cotton acreage planted that year. Moreover, the tobacco budworm population sampled at the site in District III was susceptible to methyl parathion and DDT-toxaphene. In 1973 and 1974, tobacco budworm samples were collected at only two and four sites, respectively. In short, it is questionable that these data are truly representative, particularly since there is general agreement that resistance may vary significantly from one location to another.

Testing for pesticide resistance generally is performed by collecting field samples of the insect and exposing them in a laboratory to various doses of the insecticides being tested. Dr. Graves, who performs this testing in Louisiana, testified that "the only usefulness of this data is to find the range which would correspond to reduction in yield with field infestations present when control is not achieved." In other words, he was underlining the importance of determining the efficacy of an insecticide at the same field location from which samples for laboratory studies of resistance are collected. This correlation of laboratory data to field efficacy data for DDT and alternatives is supported by data from only one location in the State (Red River Valley, 1972). The State apparently relies on the data from this one study to show that methyl parathion failed to control tobacco budworm when there was a five-fold increase in resistance, while DDT-toxaphene remained effective when there was a two-fold increase in resistance.

Other data presented at the recent hearings on Louisiana's application raise a question about the extent to which reliance can be placed on just one lab-field correlation. USDA representatives introduced a report (Adkisson and Nemec, 1966. Comparative Effectiveness of Certain Insecticides for Killing Bollworms and Tobacco Budworms. Tex. Agr. Exp. Sta. B–1048) which showed that a seven-fold increase in resistance to DDT-toxaphene can be associated with an inadequate level of insecticidal efficacy, i.e., only 21 percent insect mortality 48 hours after treatment. Of the 12 sites sampled in Louisiana in the 1972–74 period at which some level of insecticide resistance was detected, seven had tobacco budworm populations greater than a seven-fold level of resistance to DDT-toxaphene.

In addition to the serious questions as to whether Louisiana's laboratory resistance data are representative of the major cotton-producing areas and whether the one lab-field correlation is meaningful, the data on this issue are deficient in that there are no data on tobacco budworm resistance to DDT-toxaphene-methyl parathion or to methyl parathion in combination with other commonly used insecticides nor any data on efficacy in the field of DDT-toxaphene vs. DDT-toxaphene-methyl parathion.

G. There will be a shortage of currently registered pesticides.

It is generally recognized that there was a shortage of cotton insecticides last year. This shortage was due largely to raw materials shortages and increased demand arising from increases in cotton acreage. From inquiries to manufacturers of insecticides registered for use against tobacco budworm, it is clear that most of them expect this year's supplies to be about the same as last year's. Since cotton acreage in the U.S. is expected to decline from nearly 14 million acres in 1974 to about 9.5 million this year, a repetition of last year's shortages is unlikely.

H. It is anticipated that tobacco budworm will be a major problem again in 1975 and will significantly reduce cotton yields.

Whether a late-season outbreak of tobacco budworm will occur again in 1975 is uncertain. There is no predictive model which would enable Louisiana to forecast the level of infestation based on factors such as overwintering populations, flight-range potential, reproductive capacity, etc.

Louisiana's application does indicate that the second-generation tobacco budworm population can be surveyed, beginning about June 15, to determine the time and areas in which damaging populations can be expected to occur and to identify areas where levels of resistance to currently available insecticides are likely to be so high that the use of the DDT mixture will be necessary.

In contrast, Dr. Roussel testified: "I have no idea how to predict budworm, but I do say and I will say that, based on the extremely mild winter we have, that our pest problem generally in the State will probably be more severe. However, that can be modified with weather conditions that exist in May, June, and July." As to the usefulness of the second-generation field surveys, Dr. Roussel testified that "it will not tell us that we will or will not have an outbreak in August."

Dr. Newsom testified that the "problem in Louisiana reached crisis proportions in 1974. It may be relatively slight, or no problem at all during 1975. Past experiences, however, indicate that it may be expected to intensify."

Though there is no method for predicting the occurrence and magnitude of future tobacco budworm infestations it seems clear that past practices in the Louisiana cotton-producing industry, if not altered, tend to increase the likelihood of an outbreak this year:

In 1972 and 1973, about 36–38 percent of the cotton growers in Louisiana used diapause control procedures, i.e., one or two late-season applications of methyl parathion to reduce the population of boll weevils going into the overwintering stage and thereby reduce the initial infestation level in the succeeding year. Whether the same percentage of growers used diapause control procedures last year is not known, but in light of the losses experienced last year, it is likely that growers were less inclined to incur the expense. In any event, it is generally agreed among entomologists that diapause control is most effective when it is employed throughout an infested area. Diapause control is related to tobacco budworm control in that it can reduce the need for in-season use of insecticides to control boll weevil infestations and thereby preserve tobacco budworm predators and parasitoids. Since boll weevil is an important pest on more than two-thirds of Louisiana's cotton acreage, any decline in the use of diapause control will tend to have a substantial influence on the tobacco budworm problem.

Because of generally favorable climate and soil, Louisiana historically has produced high yields of cotton. Naturally, the higher the yield is, the higher a grower's income will be. Until recently, therefore, cotton growing in Louisiana has been oriented toward maximum production through the use of indeterminate or late-season varieties of cotton and extensive use of fertilizer, herbicides, and insecticides. Until insecticide resistance appeared in the tobacco budworm, this practice was understandable. In 1975, because of the anticipated difficulty in controlling late-season tobacco budworm infestations, the State's Guide for Cotton Insect Control will make the following recommendations:

Avoid late planting.

Use nitrogenous fertilizers moderately.

Delay insecticide applications as long as possible. Apply insecticides only when insects reach damaging levels.

Plant soybeans when cotton cannot be planted within the recommended planting interval, i.e., April 20–May 15.

This year will be the first one in which the first, second, and fourth recommendations have appeared in the Guide. It is likely that many farmers will be hesitant to follow these procedures until their advisability and economic feasibility have been clearly demonstrated. To the extent that they ignore these recommendations, the potential for another tobacco budworm outbreak will be increased.

I. The requested use of DDT poses no unreasonable risk to human health.

No human health data were included in Louisiana's application. To the extent that such data were included in testimony at the public hearings, the data were almost entirely derived from studies performed and reported prior to the DDT cancellation action. Additionally, the only human health information cited by the State of Louisiana in its summary of "substantial new evidence" consisted of quotations attributed to an EPA official extracted from a House Agricultural Subcommittee hearing record. At least one portion of the alleged quotation cited—i.e. "Thus subsequent evidence confirms that human risk is remote and that the limited use in question poses no unreasonable risk of harm to man" (Petition for Reconsideration, at p. 6)—does not even appear in the Subcommittee hearing record. None of the brief comments made in other summary statements is supported by any evidence that would contradict the findings on human health that were set forth in the DDT cancellation order. Moreover, the recent Aldrin/Dieldrin suspension order found that DDT reacts with another ubiquitous environmental contaminant, Dieldrin, to produce synergistic carcinogenic effects. (Order of the Administrator, at p. 31).

J. Cotton growers will use DDT in accordance with a program designed to control its use and minimize environmental impact.

In the DDT cancellation order, the Administrator's statement of general findings including the following:

"No directions for use of DDT, even if followed, can over the long run completely eliminate DDT's injury to man or other vertebrate animals."

"No warning or caution for use of DDT, even if followed, can over the long run prevent injury to living man and other vertebrate animals and useful invertebrate animals."

"The use of DDT in controlled situations in limited amounts may present less risk than usage in greater amounts, but still contaminates the environment."

Exactly what would constitute a "controlled situation" or "limited amounts" is not defined.

Louisiana's application specifies that "no DDT will be applied until the occurrence of the tobacco budworm has been confirmed at population levels at or above the economic injury threshold" and describes a field survey program and related distribution control measures to implement this commitment. Louisiana's officials' testimony indicated that a detailed operational plan has yet to be prepared. Nor was any estimate offered as to the extent to which this program can be expected to reduce the use of DDT below the projected maximum of five applications per acre to every acre of cotton in the State.

Louisiana's application also identifies a number of regulatory restrictions and educational measures designed to minimize environmental impact. Regulatory restrictions would include a mandatory half-mile separation between DDT spraying and dairies or forage, silage, and grain crops used to feed dairy animals; a similar restriction—with exact distance to be determined by testing prior to use of DDT—will be applied to spraying in the vicinity of grazing areas for beef cattle. Educational measures would include urging farmers to plant alternative crops in areas that are extremely sensitive to DDT, e.g., near pastures; to harvest hay, silage, and grain crops before use of DDT begins; to consider prevailing wind direction in planting cotton so that drift will be away from sensitive areas; and so on.

Assurances were given that implementation of the various regulatory and educational measures is practicable. There was testimony that cotton growers can be expected to be highly responsive to the program. State officials rejected the suggestion that some or all of the voluntary measures should be mandatory. They indicated that 35 State employees would be charged with monitoring compliance. Legislation to be considered when the State legislature convenes next month would provide for a penalty of up to $500 for violation of any of the regulatory restrictions.

Following its description of the measures designed to control the use of DDT and limit environmental impact, Louisiana's application asserts:

"It is recognized that the use of DDT, even when the precautions outlined above are taken, will result in widespread contamination of the environment with undesirable residues of this chemical. However, the amount that will be used for this emergency will be no more than one-fourth to one-third of that used each year for more than two decades without any evidence of irreversible adverse environmental effects."

Elsewhere, it asserts:

"Except for isolated residue problems in selected commodities, it is not expected that the use of DDT will curtail the range of beneficial uses of the environment. Even the most severe of the localized effects are unlikely to be of more than extremely short duration."

In the course of the recent hearings on Louisiana's application, there was testimony from representatives of the Governor's Council on Environmental Quality, the Stream Control Commission, and the Fish and Wildlife Commission, all of whom subscribed to the foregoing statements. In response to questions, however, neither they nor any other State officials could cite any analysis that has been done to project environmental impacts with and/or without the various use control and environmental protection measures. One State representative sought to minimize the significance of the statement concerning undesirable residues by saying that any DDT residue is undesirable.

Louisiana officials seem to be implicitly agreeing with the Administrator's general findings as to the inevitability of environmental injury when DDT is used. No significant new scientific data were presented to refute these findings. They also seem to be saying that the requested use would involve a limited amount in a controlled situation, but no analysis of the anticipated effectiveness of the control measures is available, and there apparently is no detailed operational plan for obtaining compliance. In short, while it may be Louisiana's position that its use control and environmental protection measures represent a significant change from the way in which DDT was used prior to the EPA cancellation action, and while it may be possible to substantiate this position, no substantiation has been offered thus far.

K. "Pest management techniques such as trap crops, resistant varieties, diapause programs, insect pathogens, etc., are not developed adequately to preclude the need for effective insecticides. Research under Louisiana conditions has shown that certain of these techniques are useful in reducing the probability of pest outbreaks but they will not replace direct chemical control when outbreaks do occur." Louisiana's application, page 22.

The key question concerning the usefulness of integrated pest management (IPM) methods in the Louisiana cotton-producing industry is not whether the use of such methods will eliminate the need for an effective insecticide for tobacco budworm control. IPM, by design, attempts to use all necessary insect control methodologies but in a sequence that will optimize the control benefits and minimize the amount and optimize the timing of insecticide applications. IPM may actually result in greater use of insecticides (Evaluation of IPM Programs for Cotton in the United States, 1974, Report to CEQ and EPA). For example, in Texas in 1973, cotton farmers participating in the IPM program used 33,686 more pounds of insecticides than did non-participating farmers, i.e., about one pound per acre more insecticide was used by participants. However, better timing of the application of insecticides and use of diapause control enabled the participating farmers to increase yields and thereby reduce the amount of insecticide used to produce a bale of cotton by 7% (i.e. 13.54 pounds of insecticide/bale without the program vs. 12.62 pounds/bale with the program).

Like any other new product, IPM methods for cotton insect control must be carefully designed and "sold" to potential users. Lacewell and Casey (1974, IPM Report to CEQ and EPA) listed the following items as necessary components of a successful program:

1. Program support by a strong producer organization.

2. Strong individual producer support o the program, coordinated through the producer group or association.

3. County extension entomologists possessing above-average competence, initiative enthusiasm, and ability.

4. A strong research component developing optimum pest management strategies and new and innovative approaches in all phases of cotton production, oriented toward local or regional climatic and other requirements, and effective flow of information between research and implementation.

5. Continued governmental support, justified by documentation of actual and potential benefits to producers as well as to society.

The potential benefits of IPM for cotton insect control have been clearly demonstrated in Texas. The crux of the IPM issue in Louisiana is twofold: 1) What is the level of the research effort in Louisiana to develop IPM as an alternative to complete reliance on conventional insecticidal control? and 2) What is the level of implementation of these methods by cotton producers in the State?

USDA conducted a survey of cotton-producing States in November 1974 to determine the extent of tobacco budworm problems and identify needed research on this problem. Both Texas and Louisiana have severe tobacco budworm problems. The difference in the research recommendations of these two States is marked, however. Basically, Texas said: Screen alternative chemical, biological, or behavior materials; place further emphasis on pest management; and develop *Heliothis* resistant cotton varieties. In contrast, Louisiana suggested: Greatly expand testing of as many new chemicals as possible; initiate a crash program on the development of synthetic pyrethroids (a conventional insecticide); seek permission to use DDT until a new chemical is registered; and give top priority to an immediate and long-range effort on resistant varieties. In short, most of Louisiana's suggestions were directed towards furhering the use of conventional insecticides.

The inadequacies of this response to the tobacco budworm problem are further compounded by the low level of grower participation in cotton IPM programs. Most of the currently used IPM methods require a nearly complete participation by growers within a large area to be effective. As an example, Dr. Brazzel, USDA (DDT Cancellation Hearing, 1972, Vol 3), stated that diapause control of the boll weevil, to be effective, would require nearly 100 percent participation of the cotton growers within the infested area. In 1973, only 38 percent of the cotton acreage was exposed to diapause control measures in Louisiana. Another method which has been proven to reduce the number of insecticidal applications necessary during the course of a cotton growing season is the use of field scouts to determine the need for insecticide treatment. In 1974, 260,000 acres, or 40 percent of the land planted to cotton in Louisiana was scouted. Dr. Clower, Professor and Project Leader for Cotton Insect Research, Louisiana State University (1974, A Statement Regarding the Plan to Eradicate the Boll Weevil from the United States) in a discussion of the feasibility of IPM techniques for use in a boll weevil eradication program stated "I personally have worked on the trap crop principle in cotton for over 10 years and feel that it offers an excellent pest management mechanism under Louisiana conditions. Louisiana is the first state to officially recommend it to growers." Yet, only 6,500 acres, or a maximum of 1 percent of the cotton acreage in Louisiana in 1974 was planted in trap crops. This figure, however, may be below the norm for the State due to excessive rainfall during the 1974 planting period.

IPM techniques, such as diapause control, trap cropping, and the judicious use of insecticides through scouting, reduce the probability of damaging pest outbreaks including tobacco budworm. The commercial feasibility of implementing these methods to control cotton insects has been demonstrated in other States. Furthermore, IPM may be used to avoid tobacco budworm outbreaks by the use of early planting and early maturing varieties of cotton. The data indicate, however, that the level of grower participation in cotton IPM in Louisiana is inadequate.

7. Conclusions.

A. Average cotton yields have declined in the last two years as compared to the preceding ten years. However, there is no evidence to indicate that any meaningful conclusions concerning the relationship of yields to the presence or absence of DDT can be drawn from such a comparison.

B. The tobacco budworm is but one of many factors which affect yields, and it is quite clear that no evidence was presented to support the proposition that the tobacco budworm was the principal cause of reduced yields in the past two years.

C. The tobacco budworm has become a late-season cotton pest; however, it is not clear that the predominance of this pest occurred as recently as three years ago; instead, it may have risen to its present status prior to 1972. Furthermore, because of resistance problems, it is just as likely that the tobacco budworm will remain a late-season pest whether or not DDT or methyl parathion or any other currently available pesticide is used.

D. The Louisiana estimates of economic losses totally ignore the numerous factors which affect cotton yields. The underlying assumptions on which the estimates are based are inconsistent with actual experience in Louisiana and are contrary to sound analytical methodology.

E. There is no conclusive evidence to indicate whether the DDT mixture can be expected to be effective in controlling tobacco budworm in 1975.

F. Louisiana has not demonstrated that all currently registered insecticides are ineffective against tobacco budworm.

G. A repetition of cotton insecticide shortages in 1974 is unlikely to occur in 1975.

H. It is impossible to predict the likelihood of a tobacco budworm outbreak in 1975 at this time. However, if past cotton production practices are continued, and more sophisticated production methods are ignored, the likelihood of an outbreak will be enhanced.

I. No evidence was offered to refute the findings contained in the 1972 cancellation order that DDT is a potential human carcinogen.

J. Adverse effects to the environment can only be minimized, not eliminated. The proposed controls for minimizing the adverse effects are laudable in some respects and lacking in others. The likelihood of these controls being carried out in the spirit in which they are proposed is subject to question because of the voluntary aspects of many of the most important controls and the considerable administrative problems posed by the use of 2.25 million pounds of DDT by large numbers of farmers covering an area which may be as large as 450,000 acres.

K. Louisiana has not taken fullest possible advantage of integrated pest management techniques which other States have found to be of considerable benefit.

ATTACHMENT A TO THE REPORT OF THE SPECIAL REVIEW GROUP

The following table is a reproduction of one contained in Louisiana's application (pg. 15) for an emergency exemption (with 1974 yield corrected to reflect more recent data presented at the public hearings):

Year:	*Pounds lint per acre*
1963	628
1964	544
1965	540
1966	502
1967	621
1968	636
1969	551
1970	555
1971	576
1972	509
Total	5,762
10 yr. average	576
1973	481
1974	430
Total	911
2 yr. average	455
Difference	121

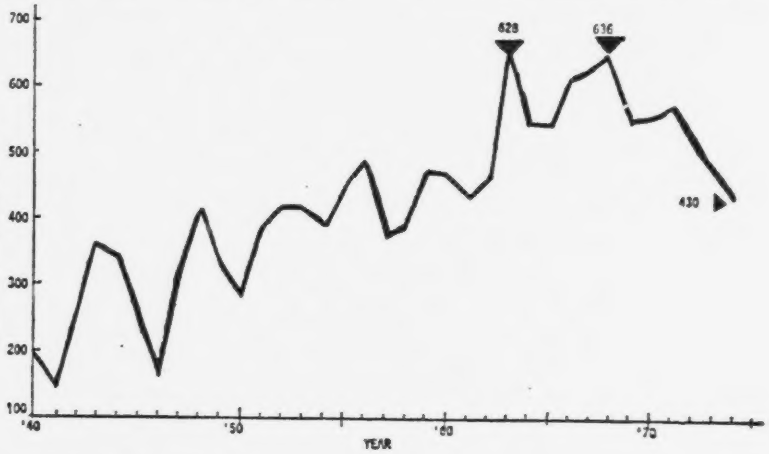

Figure 1. Louisiana Cotton Yield for the Years 1940 through 1974 in Pounds per Harvested Acre.

Attachment B of the Report of the Special Review Group

ATTACHMENT C TO THE REPORT OF THE SPECIAL REVIEW GROUP

ANALYSIS OF EFFICACY DATA

In this analysis of Louisiana's data on the efficacy of the DDT mixture and other insecticides, the standards used in evaluating the data are identified (underlined), and the findings are related back to the standards. When a pesticide proposed for use in an emergency situation is one which has been cancelled after extensive administrative inquiry, it is appropriate that reasonably rigorous standards be applied to the supporting data. Otherwise, the mere assertion that an emergency exists, even if well substantiated, would leave EPA without any meaningful basis for judgment as to the efficacy of the proposed solution. In an emergency, even more than in routine pest control situations, it is vital that the pest control method to be used be effective, particularly since the consequences of using an ineffective method could be much more serious.

A. What is the pretreatment infestation level? If multiple pest species are involved, what are the relative proportions of the various species during the course of the test?

The tobacco budworm and the bollworm are two closely related species belonging to the genus *Heliothis* and are similar in appearance to the naked eye. In the efficacy data tables in Louisiana's application (pp. 27–32), presenting the results of testing in 1972–74 at experiment stations in Northeast and Northwest Louisiana, the State's two principal cotton-producing areas, neither the pretreatment infestation levels nor the relative levels of tobacco budworm and bollworm are specified. Comments related to Tables 1, 3, and 5 assert that tobacco budworm was the primary pest during September, but exact figures were not given there or in testimony at the recent hearings. Proper experimental design would have included sampling in the untreated check plots to determine infestation levels and relative proportions of tobacco budworm and bollworm before and during pesticide testing. In the absence of such sampling data, the exact impact of the tobacco budworm and the efficacy of the chemicals tested cannot be determined. All that can be said is that control of *Heliothis* was or was not achieved.

B. Were the infestation levels before treatment and during the testing significant?

Though pretreatment infestation levels were not determined, the data in Tables 1–5 for untreated check plots indicate heavy infestation pressures during the course of the experiments. The significance of these infestation pressures are manifest in the reported yield differences between treated and untreated plots.

C. Did the pest infestation occur at a point during the development of the host plant (cotton) which resulted in a significant impact on yield or crop quality?

As indicated in B, it is apparent from the data on untreated plots that the *Heliothis* infestations did occur during a critical period in the development of the cotton plants, except that the comment related to Table 1 is that "this infestation occurred too late to have a maximum impact on production, hence inferior treatments still produced relatively good yields."

D. Was the experiment designed properly to eliminate or account for the impact of independent variables, e.g., boll rot, climatic stress, presence of other insect pests, and therefore clearly demonstrate the impact of the insecticide treatment?

The test data reported in Tables 1–5 were derived from testing using a replicated, random block design. Though this design does not isolate independent variables, the use of untreated check plots does make it possible to account for the impact of such variables. This type of experimental design is widely accepted by entomologists. A conditional or multiple regression analysis would have been useful in assessing the relative importance of the several variables which might have affected yield; no such analysis has been presented.

E. Was the use of the insecticide related to a reduction in the target insect population?

Tables 1–5 provide no data on the impact of any insecticide on the total *Heliothis* numbers or, in particular, tobacco budworm. Louisiana's evaluation of the insecticides is based on levels of damage to squares and bolls and on production of seed cotton per acre. These indices are useful, of course, but absence of data on numbers of insects before and after treatment adds to the difficulty of evaluating efficacy against the tobacco budworm. This problem is exemplified by the data in Table 1 showing that treatment with phosvel resulted in a lower level of boll damage (2 percent) than did treatment with the DDT mixture (5 percent); however, yield in the DDT mixture-treated plot was higher. USDA's Dr. Richard Ridway testified that in his efficacy tests he tries to include estimates of the tobacco budworm population in the test plots.

F. Can comparisons of the efficacy of the test material vs. registered standards be made in order to determine relative efficacy?

The relative efficacy of the DDT mixture vs. registered alternatives is a key question. In the absence of direct comparisons of the DDT mixture to the registered alternatives tested in 1973 and 1974 (Tables 3–5), it is inappropriate to use these data to support the contention that use of the DDT mixture is essential. The logical question is whether the DDT mixture would have been effective in 1973 and 1974; this question cannot be answered with Louisiana's data. It is noteworthy that USDA did not include Tables 3–5 in its analysis of Louisiana's application.

G. Have any of the insecticides demonstrated any adverse effects in terms of phytotoxicity?

Louisiana officials testified that methyl parathion has been found to cause delays in maturation of cotton plants; however, no data on this point appear in the State's application. In addition, a review of the scientific literature indicates that no significant phytotoxic effects were noted in a test comparing DDT-toxaphene and DDT-methyl parathion.

H. Were the variations in insect populations and damage and yield estimates analyzed statistically to determine if they were statistically significant?

The only statistical analysis presented by Louisiana is a test of the statistical significance of yield in treated vs. untreated plots. For the insecticide testing performed in 1972, this analysis showed that, in addition to the DDT mixture, all five registered alternatives tested at the Northeast Louisiana experiment station and two of five tested at the Red River station in Northwest Louisiana yielded significantly more seed cotton per acre than was derived from untreated plots. No multiple-range type analyses were presented; such analyses would have permitted evaluation of the significance of differences in insect damage and yields among the various chemicals tested.

[FR Doc.75-9082 Filed 4-7-75;8:45 am]

(FRL 336-1)

STATE OF LOUISIANA REQUEST FOR EMERGENCY USE OF DDT ON COTTON

Statement of Reasons for Denial

Order and Determination of the Administrator that Reconsideration of the Agency's Prior Order of Cancellation of DDT for Use on Cotton is Not Warranted.

The history of prior administrative and judicial proceedings involving the regulation and curtailment of the use of DDT is long and involved. A summary of those prior proceedings is contained in the preamble of my recent promulgation of Subpart D of the Environmental Protection Agency's ("EPA") Rules of Practice for Applications Under sections 3 and 18 to Modify Previous Cancellation or Suspension Orders (40 F.R. 12261). The culmination of those proceedings came in June, 1972, with the issuance, by former EPA Administrator William D. Ruckelshaus, of a final order cancelling virtually all uses of DDT (37 FR 13369).

On February 10, 1975, EPA published notice in the FEDERAL REGISTER (40 FR 6229) of the request by the State of Louisiana, under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended ("FIFRA"), and regulations thereunder, for the use of pesticides containing DDT (1,1,1-trichlorophenyl ethane) on cotton to control the tobacco budworm. EPA also published notice in the FEDERAL REGISTER (40 FR 6228) of informal public hearings with respect to Louisiana's application. The hearings were subsequently held in Baton Rouge, Louisiana, on February 27 and 28, 1975 and in Washington, D.C., on March 3, 4 and 5, 1975.

On March 12, 1975, EPA announced revised procedures with respect to applications such as Louisiana's which in substance seek modification of prior cancellation orders. These procedures are required by virtue of the fact that modification of a final order without a formal hearing would undercut the statutory scheme of FIFRA and prejudice the rights of parties who participated in the lengthy cancellation hearings. A more detailed statement of the reasons for adopting these procedures is set forth in the preamble to the Rules of Practice for Applications Under sections 3 and 18 to Modify Previous Cancellation or Suspension Orders which I signed on March 12, 1975, and which I incorporate by reference herein. Prior to the holding of informal hearings on Louisiana's application, a seven-man panel of EPA technical and administrative experts was appointed to hear the testimony presented at the hearings, review all exhibits submitted by the participants, and analyze the statements submitted by all interested parties which summarize the evidence bearing on the Louisiana petition. This panel was also charged to review the whole of the data and make a preliminary assessment as to whether

(1) "the applicant has presented substantial new evidence which may materially affect the prior cancellation or suspension order and which was not available to the Administrator at the time he made his final cancellation or suspension determination and (2) such evidence could not, through the exercise of due diligence, have been discovered by the parties to the cancellation or suspension proceeding prior to the issuance of the final order." (40 CFR 164.132(a)).

The report and conclusions of the panel were presented to me on Thursday, March 13, 1975. The panel concluded that Louisiana had not presented any substantial new evidence which may materially affect the 1972 Cancellation Order. The report and conclusions of the panel will be published in the Federal Register along with the statement of reasons in support of my order and determination.

Having reviewed and discussed the report and conclusions of the panel I have made a separate evaluation of the factors involved in the Louisiana situation including consultation with the EPA staff and summary statements filed by the parties to the informal hearings.

Because of the extraordinary time constraints necessarily present in this case and the need to announce my determination as soon as possible in order that Louisiana farmers can proceed with spring planting arrangements. I am announcing my determination today and deferring publication of the complete statement of the basis for my determination until next Monday, March 17, 1975.

The environmental impact resulting from the amount of DDT projected for the Louisiana application gives me cause for great concern. No evidence was presented that would refute the finding in 1972 that DDT is a mobile, persistent compound that is uncontrollable in the environment even when used in accordance with strict directions for use. Thus, the use of several million pounds of DDT in Louisiana will likely result in wide scale environmental contamination. The finding in 1972 that DDT poses a cancer risk for man is still true today. In fact scientific experimental evidence generated since the June, 1972, decision tends to reaffirm and augment this cancer hazard. In additien to the added risks to man and wildlife, there are various commercial fish, livestock and feed industries likely to be affected economically by the resulting residues. I could find no new substantial evidence that might materially change the 1972 findings.

In addition, I could find no new substantial evidence on the benefit side of this use of DDT. The best available evidence indicates that fluctuating weather conditions, national overplanting of cotton, crop subsidy, price, and other economic factors tend to have a greater impact on reduced cotton yields in Louisiana than the tobacco budworm insect.

Alternative controls are available to Louisiana farmers. Other pesticides—for example, Galecron, EPN, and methyl parathion, coupled with proper application timing—have been shown to be effective and are expected to be available in sufficient quantity this year. Farmers in the Brazos Valley of Texas and the Arkansas Delta have controlled budworm problems without DDT, using integrated pest management, such as "scouting," and by using alternative pesticides. Early planting also appears to reduce the susceptibility of cotton to tobacco budworm infestation.

The record further indicates that it is feasible to plant alternative crops that do not have similar insect problems and which can produce valuable food and feed products.

Accordingly, the section 18 application by the State of Louisiana for emergency use of DDT on cotton in 1975 is denied. A more detailed description of the reasons for this order will follow on Monday, March 17, 1975.

Dated: March 14, 1975.

Russell E. Train,
Administrator.

[FR Doc.75-9080 Filed 4-7-75;8:45 am]

[FRL 356-3]

STATE OF LOUISIANA REQUEST FOR EMERGENCY USE OF DDT ON COTTON

Supplemental Statement of Reasons for Denial

Supplement to the Order and Determination and Statement of Reasons for the Order and Determination of the Administrator that Reconsideration of the Agency's Prior Order of Cancellation of DDT for Use on Cotton is Not Warranted.

On June 30, 1972, former Administrator Ruckelshaus cancelled virtually all Federal registrations of DDT—including use on cotton. (37 FR 13369) (1972 Order). That 1972 Order was then affirmed by the U.S. Court of Appeals for the District of Columbia. See *DDT V*, Statement at 17–18. Since that time EPA has received and denied approximately 44 separate requests to use DDT on cotton on the basis that considering the general human and environmental risks associated with such DDT use, the applicants failed to establish sufficient new information to warrant approval of the request. Statement at 23. On January 24, 1975, the State of Louisiana applied for a specific exemption under section 18 of the Federal Insecticide, Fungicide, and Rodenticide Act, as amended (FIFRA) for the application of 2.25 million pounds of DDT to control the tobacco budworm on approximately 450,000 acres of cotton. By "Order and Determination" of March 14, 1975, I denied the request. A full statement of my reasons was set forth in my 50 page March 17, 1975, "Statement of Reasons for the Order and Determination of the Administrator that Reconsideration of the Agency's Prior Order of Cancellation of DDT for Use on Cotton is Not Warranted" (Statement). That Statement summarized the extensive prior administrative and judicial determinations relating to DDT. On March 21, 1975, the State of Louisiana and the U.S. Department of Agriculture (USDA) petitioned for reconsideration of my March 14, 1975, Order and my March 17, 1975, Statement. These pettions alleged various grounds for reconsideration including comments contained in a report given on March 19, 1975, to the EPA Hazardous Material Advisory Committee by an Ad Hoc Study Group (Ad Hoc Group).[1]

FIFRA section 18 provides that "the Administrator may, in his discretion, exempt any Federal or State agency from any provision of this Act if he determines that emergency conditions exist which require such exemption." I have determined that in cases such as Louisiana's—where pesticide use has been cancelled by final order after exhaustive proceedings involving the same issues—this discretionary power of exemption should only be exercised in accordance with appropriate procedures. Such procedures are necessary in order (1) to assure that public resources will not be wasted in repeated administrative litigation of questions which will not materially affect the prior order and for which an opportunity for thorough adjudicatory hearings has already been provided and (2) to provide that if substantial new evidence is presented which may materially affect the prior order the discretionary exemption power will not be exercised so as to modify the prior order without giving the parties to the original proceeding an opportunity to participate in a formal hearing on the particular questions presented. These considerations led me to adopt modifications of the Rules of Practice which govern such EPA hearings. See 40 CFR 164.130 (40 FR 12261).

In the case of the Louisiana petition the State has now had a full opportunity to present additional information in 5 days of public hearings held solely for that purpose. During the February and March, 1975, hearings on the Louisiana application 93 witnesses were heard, 1180 pages of transcript were generated and more than 1080 pages of exhibits were introduced.

After these additional hearings had been completed, I reviewed the written summary statements filed by the parties, considered the conclusions of the EPA seven-man panel (EPA Review Panel) which heard the testimony and held informal discussions with my staff and with the Ad Hoc Group. I then concluded that there was no substantial new evidence which may materially affect the 1972 Order and I denied the petition.

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[1] The Ad Hoc Group spent Friday, March 14, 1975 reviewing the Louisiana application and discussing it with representatives of the State, the USDA and the EPA Review Panel. The Ad Hoc Group reviewed the Louisiana application but did not hear any of the testimony at the 5 days of public hearings nor was it able in the one day available to it to read the 1080 pages of exhibits submitted, to consider the additional written statements filed by the U.S. Department of Interior-Fish and Wildlife Service, the Environmental Defense Fund, the Health Research Group, USDA or Louisiana or to review the 50 written comments received from the public pursuant to EPA's February 10 Federal Register Notices.

After reconsidering the record in this proceeding and the petitions for reconsideration as well as the conclusions of the EPA Review Panel and the comments of the Ad Hoc Gorup, I deny the requested reconsideration and state as basis for my denial the following:

CANCER RISK TO MAN

First, there is no new evidence which casts doubt on the 1972 findings that continued use of DDT poses a cancer risk to man. Post-1972 laboratory studies confirm the carcinogenic properties of DDT. Administrator Ruckelshaus found in 1972 that "there is no adequate human epidemiological data on the carcinogenicity of DDT, nor is it likely that it can be obtained." (37 FR 13375). There are no post-1972 human epidemiological studies which disprove or contradict this finding concerning the human cancer risk of DDT. When we deal with cancer we deal with a matter of grave concern. The 1972 findings did not, of course, conclude that DDT causes cancer in man; the 1972 findings concluded that DDT poses a cancer risk to man. Science provided no conclusive answers in 1972, and no such conclusive answers to the human cancer risk are available today. What remains, however, is clear and uncontested evidence of DDT's ability to induce cancer in laboratory animals. As former Administrator Ruckelshaus concluded in his 1972 DDT findings (37 FR 13375, IV, A, 9(c)), and as I recently stated in my Order suspending registrations of aldrin/dieldrin, given our uncertainty about the precise mechanisms that cause cancer and given the lack of adequate epidemiological studies on such ubiquitous environmental contaminants, "I believe that a carcinogenic reaction in any species of test animal must be considered sufficient to describe the test compound as a carcinogen and so a threat to human health." (39 FR 37270). In the face of laboratory data demonstrating carcinogenesis, regulatory decisions which directly affect the public health cannot be deferred—with concomitant irreversible human exposure—pending completion of epidemiological studies which require many years, are often of questionable significance and in any event provide data for making public health decisions only after the public health may have been irreversibly jeopardized.[3]

ENVIRONMENTAL RISKS

Second, there is no new evidence which casts doubt on the 1972 findings that continued use of DDT poses serious risks to fish and wildlife. None of the participants in the recent hearings on Louisiana's petition presented evidence contesting the basic environmental findings of former Administrator Ruckelshaus. In the 1972 Order he found that "once dispersed, DDT is an uncontrollable, durable chemical that persists in the aquatic and terrestrial environments." 1972 Order, 37 F.R. 13370. He concluded that DDT was "highly volatile" (37 FR 13370 n. 16) and "can vaporize from crops and soils" (37 FR at 13375); that it "can be transported by drift during aerial application" (Id. at II, A, 3(a)); and that it "can be attached to eroding soil particles" (Id. at II, A, 3(c)). Administrator Ruckelshaus also found that DDT "can persist in the soils for years and even decades" (Id. at II, A, 1); that it "can persist in aquatic ecosystems" (Id. at II, A, 2); and that "it is occasionally found in remote areas or in ocean species, such as whales, far from any known area of application" (37 FR at 13370–71). As a result of its persistence and mobility, he found that DDT is "concentrated in organisms and transferred through food webs" (37 FR 13375); that DDT "accumulation in the food chain and crop residues results in human exposure" (Id. at III, A, 2); and that "human beings store DDT" in their tissues (Id. at III, A, 3).

These inherent characteristics of DDT are particularly important in view of the uncontested findings of Administrator Ruckelshaus that the 1972 evidence "compellingly demonstrates the adverse impact of DDT on fish and birdlife." 1972 Order, 37 FR 13371. No new evidence has been introduced and none has been cited by USDA or Louisiana which undercuts this prior finding.

Moreover, no evidence has been offered by Louisiana or USDA to contest the specific 1972 findings of adverse environmental effect:

1. DDT affects phytoplankton species' composition and the natural balance in aquatic ecosystems.
2. DDT is lethal to many beneficial agricultural insects.
3. DDT can have lethal and sublethal effects on useful aquatic freshwater invertebrates, including arthropods and molluscs.
4. DDT is toxic to fish.
5. DDT can affect the reproductive success of fish.
6. DDT can have a variety of sublethal physiological and behavioral effects on fish.
7. Birds can mobilize lethal amounts of DDT residues.
8. DDT can cause thinnings of bird eggshells and thus impair reproductive success. (1972 Order, 37 FR 13371 at IV, A, 1–8).

Not only is there no new evidence which would reduce the environmental hazards previously found, but Louisiana's application for use of DDT candidly states that: "The undesirable features of once more applying DDT to large areas of cropland are recognized." Louisiana Application at 5. Many of these undesirable features have been recited in Louisiana's application which contains a brief statement of the Louisiana Wildlife & Fisheries Commission. Because it was formally adopted by the Commission with respect to the State's requested DDT use and because it shows the applicability of many of the general environmental hazards of DDT to the specific environment of Louisiana and surrounding areas, I find it appropriate to quote the entire statement as follows:

STATEMENT BY THE LOUISIANA WILDLIFE AND FISHERIES COMMISSION ON EFFECTS OF DDT ON WILDLIFE

The EPA will be petitioned to life the ban against DDT for the control of the tobacco budworm and the pink bollworm in cotton during the 1975 growing season. The Louisiana Wildlife and Fisheries Commission has been asked to comment on the impact of this insecticide on fish and wildlife.

There is documented evidence that DDT (metabolites), which is one of the chlorinated hydrocarbons, is very persistent in the environment and has been detected in high concentrations in fish, birds and mammals. Actual damage has occurred in the form of direct mortality, reproductive failure, and behavioral changes. DDT is acutely toxic to fish, shrimp, crabs, less toxic to birds and mammals. DDT applied on land areas through natural drainage will find its way into the marine environment along the Louisiana Coast. Examples of damage are listed below:

I. Mortality of Penaeid (Brown & White) Shrimp[1] occurs at 0.15 ppb (parts per billion) and bioassays conducted in Mississippi indicate 50 percent of the freshwater shrimp[2] tested over 24 hours and in four

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[3] The only "evidence" submitted by Louisiana or USDA (and referred to by the Ad Hoc Group) on the human health risks associated with DDT use is an April, 1974, quotation from an EPA official to the effect that: "There is, at the present time, no evidence that DDT is carcinogenic (or tumorgenic) in any animal species when administered at levels less than two orders of magnitude higher than the maximum dose attainable by plant manufacturers and workers over a lifetime of exposure." I have consulted with the official involved and find that he estimated the "maximum dose" of DDT plant workers to be approximately 0.257 mg/kg/day. Two orders of magnitude higher than that would be 25.7 mg/kg/day. These estimates are derived from Laws, et al, 1967. At the time of the 1972 Order the lowest dosage which had produced tumors in laboratory animals was 37.5 mg/kg/day (250 p.p.m.). Accordingly, as of 1972, tumor induction had not been confirmed in laboratory animals at feeding levels lower than a level two orders of magnitude higher than estimated maximum plant worker intake. (Maximum intakes estimated according to Ortelee, 1958, were 0.57 mg/kg/day and two orders of magnitude greater than that would be 57 mg/kg/day.) This comparison is interesting, but does not cast doubt on the 1972 finding of cancer risk to man. Moreover, the EPA official in question had not, at the time of his statement, had an opportunity to review post-1972 DDT carcinogenic laboratory studies. These studies indicate DDT tumor induction in laboratory animals at feeding levels as low as 0.3 mg/kg/day (2 p.p.m.) (see Statement at 32–33), a level comparable to Law's estimated maximum intake of plant workers (0.257 mg/kg/day) and substantially lower than Ortelee's estimated maximum worker intake (0.57 mg/kg/day).

The Louisiana petition also refers to a November 28, 1974, letter of Dr. Lloyd Tepper. That letter summarized various DDT cancer data, but did not undercut the 1972 finding of the human cancer risk posed by DDT. The pre-1972 data referred to by Dr. Tepper had been considered in the 1972 Order. The post-1972 data referred to by Dr. Tepper confirm the carcinogenesis of DDT in the laboratory mouse and the positive correlation between such a finding and broader carcinogenic effects in other species.

[1] American Fisheries Society, Volume 101, No. 3, 1972, Nimmo, D. R.

[2] American Fisheries Society, Volume 99, No. 4, 1970, Page 696, Fugerson, Denzel.

> different locations were killed at the following concentrations: 2.6 ppb, 6.8 ppb, 5.7 ppb, 3.7 ppb.
>
> II. DDT is toxic to fish,[3] killing half the following fish exposed 96 hours at concentrations of: Bullheads, 5 ppb; Goldfish, 21 ppb; Minnows, 19 ppb; Carp, 10 ppb; Bluegill, 8 ppb; Bass, 2 ppb.
>
> Other bioassay reports indicate a 96 hour tim 50 on bluegills ranging from 7 to 16 ppb.
>
> III. DDT causes thinning of egg shells and consequent critical reduction in hatching success of pelicans,[4] sea gulls, woodcock and various raptors. Direct mortality to pelicans has been attributed to DDT on birds obtained from Florida and held at the Rockefeller Refuge.
>
> IV. Robert L. Rudd states in his book "Pesticides of the Living Landscape", that half of the reptiles and amphibians are killed where DDT is used at the rate of 1 pound per acre.
>
> V. Toxicity of Crawfish—half were killed when exposed to 0.6 ppm over 24 hour period.
>
> High DDT residues found in fish resulted in the closing of Mossy and Wolf Lakes in Mississippi to commercial fishing and a warning to the public against eating excessive amounts of the fishes from these lakes, effective July 6, 1971.
>
> Completion Report F-25-1, 1970, "A Monitoring of Pesticide Levels and Water Quality of the Major Drainage Ditches Entering Wolf Lake, Mossy Lake and Broad Lake," Mississippi Game and Fish Commission, Cotton and Herring.
>
> The significance in this action is that direct economic losses have been incurred as a result of DDT residues affecting the marketability of commercial fish. The woodcock season in New Brunswick was recently closed. The stated reason being high concentrations of DDT in muscle tissues of these birds. This is a direct recreational loss.
>
> Adopted: January 13, 1975, by the Louisiana Wildlife and Fisheries Commission.
>
> See Louisiana Application at 52–53.

The Ad Hoc Group reported that it also believed that the 1972 findings of the environmental hazards of DDT are applicable to the requested use of 2.25 million pounds in Louisiana this year. Ad Hoc Group at 4.

The Ad Hoc Group concluded, however, that "The environmental ramifications appear to be limited to Louisiana." Id. at 5. In support of this conclusion the Group stated that the "area to be treated is over 100 miles north of the Gulf of Mexico * * *," that "all drainage ways [for the treated area] end up in the Atchafalaya River and Atchafalaya Bay * * *" and that none of the areas in question "drain into the Mississippi." Id. I reject this conclusion of the Ad Hoc Group. Given the volatility of DDT, its demonstrated ability to drift during aerial application and its ability to move with eroding soil particles,[6] I am convinced that environmental contamination resulting from the aerial and ground application of 2.25 million pounds in Louisiana will not be confined to Louisiana. (See also Statement by the Louisiana Wildlife & Fisheries Commission on Affects of DDT on Wildlife at second paragraph, infra.).

Much more important, however, it is no consolation to the citizens of Louisiana or to the Louisiana commercial shrimp and fish industries that DDT contamination from this use will be confined to the State and will drain off into the Atchafalaya River Basin and Bay. This area is one of the most fertile and sensitive fish and wildlife habitats in the Southeastern United States, providing habitat for the breeding and rearing of vast numbers of aquatic and terrestrial species including bass, bullheads, bluegills, crayfish, crabs, deer and woodcock. Fears of the toxic effects of DDT on commercial shrimp species caused the Louisiana Shrimp Association to oppose the requested exemption for DDT use in Louisiana. The Association maintained that any anticipated benefits to cotton farmers would be outweighed by the risk to Louisiana's shrimp and other commercial fish industries. The Ad Hoc Group also concluded that "there is concern about the hazard to juvenile shrimp downstream from the cotton growing area." Ad Hoc Group at 5.

In addition, it is not contested that even with the educational and regulatory restrictions proposed by Louisiana, as a result of the inherent characteristics of DDT serious adverse environmental effects will occur. In its application Louisiana stated that:

> It is recognized that the use of DDT, even when the precautions outlined above are taken, will result in widespread contamination of the environment with undesirable residues of this chemical. Louisiana Application at 10.

The Ad Hoc Group states that approvals of two limited and controlled applications for use of DDT subsequent to the 1972 Order for control of the tussock moth and pea leaf weevil, were "contingent on the agreement to conduct monitoring studies under EPA surveillance" and that this information "should be pertinent to subsequent requests." The quantities of DDT requested by Louisiana for the cotton acreage involved are approximately 6⅔ times greater per acre than that authorized for the Douglas-fir Tussock Moth. Even in the case of the significantly reduced quantities of DDT authorized for the tussock moth, however, in a summary document submitted to me by the U.S. Department of Interior, Fish and Wildlife Service, the Department expressed its opposition to the Louisiana request and stated that the tussock moth control monitoring program "reinforced our fears that the environment would be unacceptably contaminated by DDT."

NEED FOR DDT

Third, there is no substantial new evidence regarding the need to use DDT which may materially affect the 1972 Order.

Witnesses for Louisiana at the recent hearings on the Louisiana application testified that there has been a declining trend in cotton yields dating back to 1968. This data submitted in support of the need for DDT show that substantial yield reductions—exceeding those during the past two years—occurred in 1969 and 1972 despite large-scale use of the DDT mixture. In fact in the year preceding cancellation of DDT, the use of DDT on cotton in Louisiana accounted for more than 53 percent of the total quantity of DDT used in the United States for all purposes. Of total nationwide use on cotton that year, the amount used in Louisiana constituted more than 63 percent. In contrast, Louisiana's 1974 cotton acreage constitutes approximately 4 percent of the nation's total. Witnesses for Louisiana also testified that many factors other than the tobacco budworm infestation and the unavailability of DDT may have affected cotton yields during the past two years.

There is no dispute that many cotton producers—not only in Louisiana but also in other places—are experiencing economic difficulties. Prices are down. Production costs are up. There is no longer a Federal subsidy for cotton. Added to the effects of these factors is the general recession affecting all sectors of the Nation's economy. The availability of DDT will not by itself determine whether Louisiana cotton producers prosper or suffer this year, particularly in light of the lack of any clear-cut evidence that the DDT mixture would be efficacious against tobacco budworm. There was testimony that economic factors alone are going to cause a sharp reduction in cotton acreage this year throughout the cotton-producing States and a shift to alternative crops. In Louisiana, this cutback itself is likely to outweigh all other factors in terms of economic impact on cotton producers and related service industries and thus on the State's economy as a whole.

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[3] American Fisheries Society 1970, Volume 99, No. 1, Page 20. Macek, Kenneth J.

[4] "Relations of the Brown Pelican to Certain Environmental Pollutants in Louisiana", Joanen, Ted.

[5] American Fisheries Society 1963, Volume 92, No. 4, Page 428, Munsey and Oliver.

[6] All of which the Ad Hoc Group specifically recognized when it stated that "the environmental hazards of DDT as reviewed in the DDT [1972] findings relating to persistence, biological concentration, and transport mechanisms are applicable [to the Louisiana situation]." Ad Hoc Group at 4. The Ad Hoc Group stated that reductions in DDT residues in soils, shell fish and migratory birds had occurred, that persistence in well illuminated ocean waters may be less than anticipated but that residues of up to 1 p.p. m. have been showing up in offshore fish livers and DDT persistence together with temperatures have been associated with bluecrab problems in Florida salt marshes. These mixed "indications" do not contradict the 1972 findings. In the year preceding cancellation approximately 12 million pounds of DDT were added to the environmental burden of the U.S. In earlier years even greater quantities of DDT had been added to our environment each year. In the two years and 10 months since cancellation no such serious annual DDT additions have occurred. Because of its mobility and bioaccumulation, it is not surprising that some reduction in soil residues in certain areas may have occurred. However, human monitoring studies show a relatively constant level of DDT and its metabolites in human tissues since cancellation. Moreover, according to the Ad Hoc Group serious DDT residues in fish have continued and in some areas past DDT uses have been associated with continued environmental problems. Accordingly, these mixed data referred to by the Ad Hoc Group do not constitute substantial new evidence which may materially affect the 1972 Order.

The EPA Review Panel thoroughly examined all of the evidence presented during the recent 5-day hearings. I adopted the report of the EPA Review Panel in my March 17 Statement. My discussion in the March 17 Statement sets forth the basis for my March 14 Order. In short, although Louisiana and other parties have had ample opportunity to do so, they have presented no substantial evidence—new or old—to support the premises that the tobacco budworm problem is new, that recognition of its occurrence and seriousness is new, or that the DDT mixture is the only insecticide that can be expected to prevent economically significant damage arising from a possible tobacco budworm outbreak this year.

Louisiana and USDA now assert that I should reconsider my decision as a result of the comments of the Ad Hoc Group. The Group stated that "one could not, in 1972, anticipate the rapid increase in resistance to methyl parathion by the tobacco budworm nor the rapid geographical spread of resistance." Ad Hoc Group at 2.

To accept this statement, one would have to ignore several important factors. By 1970 near total resistance to methyl parathion and all other chemicals commonly used for control of the tobacco budworm had already developed in the Tampico and Matamoros areas of Mexico and in the Lower Rio Grande area of Texas as a result of massive use of this and other compounds and resulting selective pressure on tobacco budworm populations. This shift from insecticide susceptibility to resistance could have been anticipated whenever chemicals were being used intensively over a large area.

In fact, Louisiana appears to have anticipated such resistance. The testimony of Dr. James Tynes, Louisiana Cooperative Extensive Service, in the recent hearings on the Louisiana application noted that, in May and June 1971, he had called attention to the problem of tobacco budworm resistance to methyl parathion and its implications for cotton production in Louisiana. In addition, in a published (May 1971) article he introduced into the record, Dr. Tynes had noted that tobacco budworm resistance to methyl parathion had been associated with difficulty in controlling an infestation in at least one location in Louisiana back in 1970. It seems apparent that the Ad Hoc Group was not aware of this testimony.

The Ad Hoc Group's statement that the DDT-toxaphene combination is "known to exhibit a synergistic effect of up to twenty-fold against moderately DDT resistant populations" is totally irrelevant to the question of the efficacy of DDT-toxaphene. It is true that combining DDT and toxaphene results in a synergistic effect against the tobacco budworm as compared to DDT alone.[4] This comparison begs the question since the application seeks the use of the DDT-toxaphene mixture and since Louisiana's own data indicate that tobacco budworm resistance to the DDT-toxaphene mixture was seven-fold or greater at seven of twelve Louisiana sites sampled in 1972–74. With such tobacco budworm resistance levels the DDT-toxaphene mix has been shown to be ineffective for control of this insect.

The Ad Hoc Group also stated that "under high population pressures the requested mixture offers the best chance of successful pest management for 1975." After hearing all the evidence in the 5-day hearings and reviewing all exhibits, together with the written statements and public comments, the EPA Review Panel concluded that there was no substantial new evidence to support such a proposition. In my March 17 Statement I adopted the report and conclusions of the EPA Review Panel. I find no additional evidence in the Ad Hoc Group statement and accordingly find no basis to change my prior decision.

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In conclusion, after reconsidering the record in this proceeding I reaffirm my March 14 Order in which I denied the Louisiana application for authorization to use 2.25 million pounds of DDT on 450,000 acres of cotton this year. I rest my reaffirmation of the prior denial on this Supplement and on my March 14 Order and my March 17 Statement, which I specifically adopt and incorporate herein by reference. There remains no substantial new evidence which may materially affect the 1972 Order with respect to the human cancer risk posed by DDT, the environmental hazards of DDT and the need to use DDT on cotton.

Dated: April 1, 1975.

RUSSELL E. TRAIN,
Administrator.

[FR Doc.75-9081 Filed 4-7-75;8:45 am]

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[4] The basis for this statement apparently comes from data published by Graves, Clower, and Bradley (1967, Resistance of the Tobacco Budworm to Several Insecticides in Louisiana) which compared the LD50 for tobacco budworms, exposed to several insecticides, collected near Transylvania, Louisiana, in 1966. In this test the LD50 for DDT was approximately 20 times greater than the combination toxaphene-DDT (2:1).

APPENDIX E

federal register

THURSDAY, JULY 3, 1975

WASHINGTON, D.C.

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PART II

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ENVIRONMENTAL PROTECTION AGENCY

■

PESTICIDE PROGRAMS

Registration, Reregistration and Classification Procedures

Title 40—Protection of Environment

CHAPTER I—ENVIRONMENTAL PROTECTION AGENCY

SUBCHAPTER E—PESTICIDE PROGRAMS

[FRL 393-4]

PART 162—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL INSECTICIDE, FUNGICIDE, AND RODENTICIDE ACT

Subpart A—Registration, Reregistration and Classification Procedures

On October 16, 1974, notice was published in the FEDERAL REGISTER (39 FR 36973) proposing regulations to amend 40 CFR 162 pursuant to the authority of sections 3 and 25 of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), as amended by the Federal Environmental Pesticide Control Act (FEPCA), Pub. L. 92-516, 86 Stat. 973, hereinafter referred to as amended FIFRA. The regulations shall read as set forth below. The intent of this rulemaking is to revise present procedures for the registration of pesticides and establish procedures for the reregistration and classification of pesticides to conform to the provisions of the amended FIFRA.

Throughout the development of these regulations, the Agency has taken every opportunity to solicit public views and comments. Beginning with the January 9, 1973, FEDERAL REGISTER notice (38 FR 1142), the Agency stated that public comments on the form and content of the regulations were invited. Moreover, the Agency in the January 9, 1973 notice set forth its "preliminary views" on the regulations, including registration. Shortly thereafter, the Agency held a number of informal public hearings on the classification and registration provisions under the amended FIFRA. Each of the views and comments received at these hearings was then considered in the development of an initial draft regulation.

As the numerous draft proposals were developed by the Agency, they were made available to all interested parties. Comments on the drafts were received from State regulatory agencies, industry, trade associations, environmental groups, other Federal agencies, and individual Congressmen. Further, representatives of the Office of Pesticide Programs discussed at length various proposals with representatives from each of these groups. The comments received were considered in evaluating the merits of each of the drafts and modifications were made where appropriate.

In July, 1974, following distribution of over 2,000 copies of the complete draft regulation the Agency held an informal public hearing in Washington, D.C. At this hearing, representatives of the Agency explained in detail the major provisions of the draft regulation and the rationale behind each provision. Attendees made formal statements, submitted written comments and raised specific questions on the draft which the officials of EPA addressed; a transcript of the hearing was taken. After consideration of the views expressed at the public hearing, the proposed regulations were published in the FEDERAL REGISTER for formal public comment.

Many interested parties complained that the comment period on the proposed regulations was too short. After consideration of these complaints, the Agency notified all interested parties that comments on the regulations would be received and considered during the period of preparation of the final regulations. Numerous comments were in fact received and considered during the several months preceding issuance of these regulations. In addition, during this same period the Agency held information meetings, on request, with as many interested parties as possible to explain the proposed regulations and modifications under consideration. As a result, written comments on the proposed regulations were received from over 200 interested parties. All of these comments have been reviewed and are on file with the Agency. Certain of these comments have been adopted and others were substantially satisfied by editorial changes, deletions from or additions to the regulations.

Finally, on a number of occasions, certain parties, representative industry groups in particular, have complained that they could not fully comment on the Section 3 regulations without having the Guidelines relating to data submissions available at the same time. These contentions are rejected for the following reasons. First, beginning as early as January, 1972, drafts of the Guidelines have been made available to all interested parties. The pesticide industry, through its representatives, has not only had an opportunity to comment on these various drafts over the last two years but has been involved in reviewing and assessing comments and in suggesting modifications. Second, the regulations establish data and evaluation criteria which are self-contained. Informed comments as to the regulations, then, did not depend on whether or not the Guidelines for testing and data development were published in the FEDERAL REGISTER for formal public comment at the same time as these regulations were so published. For these reasons, it is believed that all affected parties have had a full and fair opportunity to comment on these regulations.

GENERAL

Passage of the 1972 amendments to FIFRA enacted through the Federal Environmental Pesticide Control Act[1] (FEPCA) was part of a wave of environmental legislation which completely overhauled Federal environmental regulatory authority. In 1970, Congress passed the Clean Air Act[2] and in 1972, along with the amendments to FIFRA, Congress enacted substantial amendments to the Federal Water Pollution Control Act.[3]

While Federal regulation of pesticides first began in 1910 and was substantially expanded in 1947,[4] the 1972 amendments completely restructured the Federal pesticide regulatory scheme and redefined its thrust. FIFRA was changed "from a labeling law into a comprehensive regulatory statute that will henceforth more carefully control the manufacture, distribution, and use of pesticides."[5] As the House Committee on Agriculture summarized in its Committee Report:

> The Committee found the greatest need for revision of existing laws to be in the areas of strengthening regulatory controls on the uses and users of pesticides, speeding up procedures for barring pesticides found to be undesirable; streamlining procedures for making valuable new measures, procedures, and materials broadly available; strengthening enforcement procedures to protect against misuse of these biologically effective materials; and creating an administrative and legal framework under which continued research can produce more knowledge about better ways to use existing pesticides as well as developing alternative materials and methods of pest control.[6]

It is clear that Congress' primary purpose in enacting FEPCA was to ensure that pesticide use was subject to a thorough environmental and human health hazard review.[7]

In keeping with this environmental and human health perspective, the amended FIFRA established many new requirements for review in connection with the registration process. This preamble discusses the new requirements, their implementation by these regulations and the Agency's responses to comments received on the proposed regulations.

COMMENTS AND REVISIONS

Section 162.2 *Principal Statutory Provisions*. Several commenters suggested that this entire section be deleted or that it track the statute verbatim. The principal statutory provisions of FIFRA relevant to the registration, reregistration and classification of pesticides are described in the regulations for the convenience of the reader who may not have a copy of FIFRA on hand. In response to the comments, several modifications have been made in the text to track the statute more closely. We reiterate, however, that any specific question of statutory interpretation must necessarily be based on FIFRA, as amended, the provisions of the substantive regulations implementing it, and any judicial interpretation thereof.

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[1] 86 Stat. 975, Pub. L. 92-516, 7 U.S.C. 136.

[2] Clean Air Amendments of 1970, 84 Stat. 1976, Pub. L. 91-604, 42 U.S.C. 1857.

[3] Water Pollution Control Amendments of 1972, 86 Stat. 816, Pub. L. 92-500, 33 U.S.C. 1251.

[4] The Insecticide Act of 1910 prohibited the interstate sale of any insecticide or fungicide which was adulterated or misbranded; however, the Act did not require registration of pesticides. The concern of the 1910 Act was the effectiveness of products and deceptive labeling. The 1947 FIFRA established a registration requirement, but authority to deny registration applications was not provided until 1964. As with the 1910 Act, the 1947 FIFRA's primary purpose was the protection of consumers from ineffective products. See *Stearns Electric Paste Co. v. Environmental Protection Agency*, 461. F. 2d 293 (7th Cir. 1972).

[5] H.R. REP. No. 92-111, 92 Cong., 1 Sess. 4 (1971).

[6] House Report, at 4.

[7] House Report, at 13, 20 and Senate Report, at 5.

Section 162.3 *Definitions*. Several commenters indicated that it is unnecessary to repeat in the regulations a definition contained in FIFRA. Those definitions which appear in FIFRA and are repeated in the regulations are either essential to the understanding of these regulations or have been given further interpretation by these regulations.

(1) Section 162.3(a) *Accident*. Several commenters suggested that the word "unreasonable" be added to the definition of this term to indicate the extent of the adverse effect upon man or the environment. These commenters misunderstand the statutory scheme of FIFRA, as amended. A finding of unreasonable adverse effect on the environment from use of a pesticide is grounds for the cancellation or the denial of the registration of a pesticide. The occurrence of an accident alone may or may not establish that a pesticide causes an unreasonable adverse effect on man or the environment. Such a determination is made after a full review and evaluation of the evidence in each case. Where the effects from use of a pesticide are found to be unreasonable, appropriate actions will be taken by the Agency.

(2) Section 162.3(c) *Active Ingredient*. (a) Several commenters asked that the word "attract" be deleted from § 162.3(c)(1). They argued that it is not included within the statutory definition of "active ingredient", and furthermore that the Agency has included several attractants as examples in its definition of inert ingredient, § 162.3(t). Amended FIFRA, at section 2(a)(1), defines active ingredient, in part, as an ingredient which will prevent, destroy, repel or mitigate any pest. Where an ingredient falls within this broad statutory standard, it will be evaluated as an active ingredient. The definition of "attractant", within the larger definition of "pesticide" at § 162.3 (ff)(3), indicates which attractants are active ingredients and which are inert ingredients. In addition, the reader is referred to the definition of inert ingredient at § 162.3(t) and the factors, listed at § 162.6(b)(2)(i)(C)(2), used by the Agency to determine whether an ingredient is active or inert. To avoid the apparent confusion caused by inclusion of the word "attract" at § 162.3(c)(1), it has been deleted.

(b) In response to comment, and in order to clarify the term active ingredient, in the case of a plant regulator, "biochemical" has been added to the definition at § 162.3(c)(2).

(c) Section 162.3(c)(2), as proposed, has been transposed to § 162.6(b)(2)(i)(C)(2).

(3) Section 162.3(j) *Application of a Pesticide*. In order to clarify that the Agency includes placement for effect of a pesticide within the meaning of "application of a pesticide", this term has been defined. The Agency feels that the definition of the term "direct application" is redundant and accordingly has deleted § 162.3(1), as proposed.

(4) Section 162.3(k) *Changed Use Pattern*. Questions arose concerning the indices the Agency will evaluate in determining whether a new use is a changed use pattern. The distinction becomes important in the notice provisions of section 3(c)(4) of the Act and the regulations thereunder. To clarify the Agency's interpretation of a changed use pattern, the term has been defined as a significant change from a use pattern approved in connection with the registration of a pesticide product. Examples of "significant" changes are included in the definition. Deletion of a significant use pattern is also included within the scope of this term so as to provide user groups with notice of these regulatory actions.

(5) Section 162.3(l) [§ 162.3(j)] [4] *Degradation Product*. The Agency intends to include within the meaning of "degradation product" a substance resulting from any transformation of a pesticide. For greater clarity the definition has been modified to read: "by physico-chemical or biochemical means." "Electromagnetic" has been deleted, pursuant to comment, to avoid redundancy.

(6) Section 162.3(k), proposed. *Delayed Reaction*. Several commenters objected that this term, as defined in the proposed regulations, was too specific and out of context compared with the other definitions of toxicity. After considering the matter, the Agency has concluded that the term is self-explanatory and should, therefore, be deleted.

(7) Section 162.3(m) [§ 162.3(l)], *Domestic Application*. (a) Several commenters correctly pointed out that the definition of "domestic application" as proposed included only application of a pesticide in, on, or around areas associated with the household or homelife and excluded use of a pesticide in many places where people are present for prolonged periods of time. They urged the addition to the category of domestic application of the use of a pesticide in a wide range of institutions including restaurants, hospitals, nursing homes, parks, playgrounds, schools, and office buildings.

The rationale for distinguishing domestic application from non-domestic application is based on an evaluation of risk taking into account the degree of competence of the user, the susceptibility of people likely to be exposed, and the potential for accidental exposure to individuals other than the user. In certain situations, these factors clearly determine into which of the two classes of application a use falls. For example, use of a pesticide in a home is a domestic application, while use in a factory or commercial institution is a non-domestic application. In other situations, however, the Agency must carefully weigh the factors to determine whether the use should be considered a domestic application and thereby be subject to the more restrictive classification criteria. Pesticides intended for application in patient care areas of health related institutions and institutions where children spend time are considered by the Agency to represent, on balance, a higher risk to the exposed population. Even though the user is likely to be competent in the use of pesticides, population groups of particular susceptibility are present in these institutions. These groups include the aged, infirmed, and young. Accordingly, these institutions have been added to the general scope of the term "domestic application" and new subparagraphs (3) and (4) have been included to give examples of the specific types of institutions the Agency considers within the scope of the term.

The suggestion that use of a pesticide in a restaurant or office building be considered a domestic application has been rejected. Not only is the user of the pesticide in these locations likely to be competent in the use of pesticides; but, moreover, population groups of particular susceptibility are not likely to be present for prolonged periods of time, and therefore, there is no reason to expect a higher incidence of accidental exposure to third parties. Adequate margins of safety exist in use of pesticides in these locations and therefore these uses are considered non-domestic.

(b) Several commenters suggested that the term "non-domestic application" be defined. Domestic application is defined in detail in the regulations. If a pesticide use does not fall within this definition, by the very terms of the definition, it will be a non-domestic application. The Agency feels that definition of the term "non-domestic application" would be redundant.

(8) Section 162.3(n) [§ 162.3(m)], *Drift*. In response to comment, the word "immediately" has been inserted to qualify "after application" and clarify the confusion over the definition, as proposed. The Agency does not consider the processes of diffusion and volatilization to be included within the term drift.

(9) Section 162.3(r) [§ 162.3(q)], *Hazard*. As with § 162.3(a), *accident*, several commenters asked that the word "unreasonable" be added to this definition to indicate the extent of the adverse effect on man or the environment. For the same reasons as explained above, in the discussion of § 162.3(a), such a modification is unacceptable. Upon the finding of hazard, there must be a separate determination of whether the hazard constitutes an unreasonable adverse effect on man or the environment.

(10) Section 162.3(s) *Immediate Container*. A new definition of the term "immediate container" has been added to clarify the labeling requirements of § 162.10.

(11) Section 162.3(w) [§ 162.3(u)] *Metabolite*. Several commenters indi-

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[4] Where section numbers have been changed between the proposed regulations and these final regulations, the Preamble refers to the section as designated in the final regulations. For the benefit of the reader, the Section number which appeared in the regulations as proposed follows immediately after the final Section number in brackets, [. . .], as appropriate.

cated that the definition of metabolite as proposed was technically incorrect. They urged that "or induced by" be deleted because metabolites are not "induced by" living organisms or by biological processes. The Agency is in accord and has deleted the same.

(12) Section 162.3(y) [§ 162.3(w)] *Mutagenic*. Several commenters suggested that the definition of this term was inaccurate. It had been defined to mean "the property of a substance or mixture of substances to induce genetic or somatic changes in subsequent generations." The Agency agrees and the language of this definition has been changed to read "changes in the genetic complement of either somatic or germinal tissue in subsequent generations."

(13). Section 162.3(bb) [§ 162.3(z)] *Oncogenic*. Many commenters objected to the use of the term "oncogenic," requesting that it be replaced by term "carcinogenic." An oncogenic effect includes induction of benign or malignant tumors. The commenters argued that this distinction should be maintained for regulatory purposes. EPA has determined that the once significant distinction between benign and malignant tumors has lost much of its validity. The federal court in its review of the Agency order suspending most uses of pesticide products containing aldrin and dieldrin recently upheld this determination as reasonable and within the discretion of the Administrator. *EDF* v. *EPA*, 510 F. 2d 1292, 1300 n 21 (D.C. Cir., 1975). EPA, therefore, rejects the proposal that this term be deleted. Several modifications to the proposed definition however, have been made for greater clarification. The phrase "induce benign or malignant tumor formations" has been added to clarify that the Agency indeed considers both to be hazardous.

(14) Section 162.3(cc) [§ 162.3(aa)] *Outdoor Application*. Several commenters asked that the term "indoor application" be defined in addition to the term "outdoor application." The term "indoor application" is not explicitly used in these regulations. Each pesticide use will be evaluated to determine if it is an outdoor application. If it is, additional criteria must be evaluated in determining the appropriate use classification. If a pesticide use is not an outdoor application, the indicators for domestic or nondomestic application, as appropriate, alone will be evaluated to determine the appropriate use classification.

(15) Section 162.3(dd) *Operated by the same Producer*. Many commenters suggested revision of § 162.5(b)(1) [§ 162.5(a)] which sets forth the statutory exemption from the registration requirement for pesticides transferred between establishments operated by the same producer solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment. In order to clarify the Agency's interpretation of the term "operated by the same producer," this phrase has been defined. The reader is referred to the discussion of Section 162.5(b)(1) below for a full explanation of that Section.

(16) Section 162.3(ff) [§ 162.3(cc)] *Pesticide*. (a) Many commenters asked that the word "attracting" and the class of pesticide, "attractant" be deleted from § 162.3(ff). They argued that "attracting" is not included within the statutory definition of pesticide. That definition reads in part: "any substance or mixture of substances intended for preventing, destroying, repelling or mitigating any pest." The Agency agrees that "attracting" does not *per se* constitute pesticidal activity and accordingly the word has been deleted from the first paragraph of § 162.3(ff). It does not follow, however, that an attractant is not a class of pesticide. The Agency takes a broad view of the definition of pesticide. Where a substance or mixture of substances is intended to prevent, destroy, repel or mitigate any pest, it is a pesticide. If an attractant falls within this statutory standard, it is a pesticide. Accordingly, "attractant" has been retained as a class of pesticide. Section 162.3(ff)(3) gives examples of substances which are and which are not considered attractants, for the purposes of the Act.

(b) The proposed regulations at §§ 162.3(ff) (1) and (4) had declared certain devices subject to the Act, pursuant to the authority conferred upon the Administrator at section 25(c) (4) of FIFRA, as amended. A commenter correctly pointed out that other classes of devices should be regulated. Accordingly for purposes of clarity and thoroughness, a new § 162.15 has been added to these regulations. The reference to devices in § 162.3(ff) (1) and (4) has been deleted. The reader is referred to § 162.15 and its explanation below.

(c) Several commenters raised questions concerning the wording of the definition of "pesticide". It has been substantially rewritten for greater clarity and thoroughness (1) to provide more exact usage of the terms "preventing, destroying, repelling or mitigating"; (2) to set forth with specificity those classes of pesticides we have evaluated; (3) to clarify that use of the unmodified term "pesticide" encompasses the active ingredient, pesticide formulation, and pesticide product; and (4) to clarify that the use for pesticidal purposes of biological-type and biologically-derived substances falls within the scope of the Act. There has been no change in the Agency interpretation of the term "pesticide".

(17) Section 162.3(hh) [§ 162.3(cc)] *Pesticide Product*. Several commenters argued that the phrase "commercial product" in the definition of "pesticide product", as proposed, was misleading. The Agency is in accord and the definition has been rewritten.

(18) Section 162.3(kk) [§ 162.3(hh)] *Residue*. Several commenters suggested that substitution of the phrase "and its metabolites or degradation products" for the phrase "dissimilation products", which appeared in the definition of this term as proposed, would be more accurate. The Agency is in accord and has substituted the same.

(19) Section 162.3(mm) [§ 162.3(jj)] *Teratogenic*. Commenters argued that the phrase "to produce or incite" which appeared in the definition of this term as proposed is inaccurate and that it should be deleted. The notion of producing a functional deviation is important and is retained, but the word "induce" has been substituted for the word "incite". Furthermore, commenters argued that use of the word "ordinarily" was ambiguous and that the word "hereditable" is improper. "Ordinarily" has been deleted. Although "hereditable" is an acceptable term, "heritable" has been inserted in its place.

(20) Section 162.3(nn) [§ 162.3(kk)] *Toxicity*. (a) Several commenters suggested that the definition of toxicity be clarified by substituting the word "pathological" for the phrase "adverse physiological", which appeared in the definition of this term as proposed. The definition has been rewritten to include both of these notions.

(b) Several commenters argued that the "90 days", which was proposed as an indicator to differentiate subacute from chronic toxicity, § 162.3(nn) (2) and (3) was inappropriate. The phrase has been deleted. Instead of 90 days, the Agency will distinguish subacute from chronic toxicity by evaluating results on the basis of "one-half the life of the organism."

(21) Section 162.3(oo) [§ 162.3(11)] *Use*. (a) Many commenters objected to the proposed definition of the term "use". They argued that it should be limited to the intentional application of a pesticide and that required supervisory, disposal and storage actions should not be included. While the term "use" is not defined in the Act, it is repeated throughout and is basic to the Act's regulatory scheme. The term's legal meaning can be construed from the provisions of the Act and its legislative history. First, the legislative history clearly establishes that the major thrust of the 1972 FIFRA was to create a statutory mechanism to regulate the use of pesticides. The "misuse" of a pesticide was made an illegal act subject to civil and/or criminal sanctions, as appropriate. Second, the provisions of the statute and legislative history set forth a Congressional concern over all dimensions of pesticide use. Pursuant to section 3(c)(5)(D) of the Act, a pesticide cannot be approved for registration unless the Administrator determines that when *used*, it will not generally cause unreasonable adverse effects on the environment. Sections 19 and 25(c)(3) explicitly provide for regulation of pesticide packaging and the storage and disposal of pesticides and pesticide containers. Accordingly, the packaging of a product and the directions for and commonly recognized practices of storage and disposal are evaluated in determining whether or not a product can be regis-

tered. Section 3(d) of the Act provides that the *use* of certain pesticides shall be restricted to application only by or under the direct supervision of a certified applicator. Therefore, both the person applying the pesticide and the supervising certified applicator are "using" the pesticide. From the comprehensive regulatory scheme of the Act, it is clear that the term "use" was not intended by Congress to be synonymous with application, but rather was intended to have a more expansive meaning which would include the direction and supervision of an actual pesticide application, the storage and disposal of pesticides, and any other actions required by the Act and these regulations.

Some questions have arisen concerning the implications of the definition of "use" in these regulations with respect to the requirement for certification of applicators. It has been suggested that the definition of use in these regulations would require that persons who manufacture, transport, store or distribute restricted use pesticides will have to be certified, because such persons are "using" the pesticides in question. This view reflects a misunderstanding of the structure of the amended FIFRA, and the scope of the certification requirement. Section 12 (a) (2) (F) of the Act provides in pertinent part, that it is unlawful to use a restricted use pesticide "other than in accordance with section 3(d). . . ." Section 3(d) requires the administrator to classify uses of pesticides for general or restricted use, and provides that in certain circumstances he must restrict the *application* of such pesticides only to certified applicators (or competent individuals under their direct supervision). Thus, the requirement for certification is only imposed with respect to *application* of restricted use pesticides. However, the Agency observes that in order to become certified, an applicator must be determined to be competent "with respect to the use and handling" of pesticides. A short explanation has been included immediately after the definition of "use" in these regulations to eliminate any possible ambiguity concerning this matter.

(b) Several commenters were confused by the definition of the term "use" as proposed. It has been rewritten for greater clarity.

(22) Section 162.3(pp) [§ 162.3(mm)] *Use Dilution*. Several commenters argued that the proposed definition of "use dilution", was misleading. The Agency recognizes that a pesticide may be applied in different concentrations depending upon the mode of application. The definition has been rewritten accordingly.

(23) Section 162.3(qq) *Use Pattern*. A new definition of "use pattern" has been included to clarify, in accordance with the term "changed use pattern", § 162.3(k), the indices the Agency will evaluate in determining whether a new use is a changed use pattern.

Section 162.4 *Status of Products as Pesticides*. This section sets forth the criteria which will be evaluated to determine if a product is a pesticide product, and therefore, within the scope of FIFRA, as amended, and the regulations promulgated thereunder.

(1) Section 162.4(a) *Determination of Intent of Use*. Whether a substance or mixture of substances is a pesticide pursuant to the Act depends upon the use for which it is reasonably intended. A commenter objected to the statement in the regulations, as proposed, that the intent may be either express or implied. There is a long standing principle at law that intent may be either express or implied. The Agency has always evaluated the express and implied intentions of the user of a product and will continue to operate on the basis of this standard.

(2) Section 162.4(b) *Products Considered to be Pesticides*. (a) A commenter objected to § 162.4(b) (3), [§ 162.4(b) (4)], arguing that a product intended for use as a pesticide after reformulation should not be considered a pesticide product. Technical compounds are currently registered by the Agency. Amended FIFRA makes no distinction between products intended for use as formulated or after reformulation, and requires that both be registered. The commenter argued that reformulation may effect significant changes in the efficacy and hazard of the pesticide product. For this very reason, § 162.6(b) (1) provides that a product registration may pertain to only one formulation and that variations in the formulation of the pesticide product require separate registrations, except as specifically provided in § 162.21(a) of these regulations.

(b) Many commenters argued that § 162.4(b) (4) [§ 162.4(b) (5)] as proposed is without statutory authority. The Section declared a product to be a pesticide if it is intended for use both as a pesticide and for other purposes and stated that such a product is subject to the misbranding provisions of section 2(q) (1) (A) of amended FIFRA, both as to its pesticidal and non-pesticidal claims. Section 2(q) (1) (A) of the Act provides that a pesticide is misbranded if "its labeling bears any statement, design or graphic representation thereto or to its ingredients which is false or misleading in *any* particular". (Emphasis added). The statute, therefore, clearly requires that false or misleading statements, concerning both the pesticidal and non-pesticidal properties of a pesticide product, constitute misbranding. This is the longstanding interpretation of the Agency. [See, extant 40 CFR 162.101(b) (3) (ii)]. In these final regulations, for purposes of organization, the reference to the misbranding provision of section 2(q) (1) (A) has been deleted from § 162.4(b) (4) and is now set forth at § 162.10(a) (5).

(3) [Section 162.4(c)] *Products Considered to be Pesticides and Drugs*. Section 162.4(c) as proposed provided that registration of a product considered to be a drug as well as a pesticide, would be dependent on approval of the substance by the Food and Drug Administration. For purposes of organization, this Section has been deleted from § 162.4 and incorporated into § 162.7(d) (1), *Criteria for Approval of Registration*, as a new paragraph § 162.7(d) (1) (vi). A complete discussion of the comments received pertaining to this Section is found below at the explanation of § 162.7(d) (1) (vi).

(4) Section 162.4(c) [§ 162.4(d)] *Products not Considered Pesticides*. (a) Many commenters objected to the interpretation of the term pesticide in § 162.4(c) (2), as proposed. It had provided that paints and other formulated coatings which are treated with a fungicide to protect the coating itself and which are not intended for preventing or destroying fungi after application to any surface are within the meaning of the term pesticide. Under this interpretation only a paint treated with a pesticide intended to protect the paint itself while in the canister would not be considered a "pesticide". The commenters have contended that the Agency's interpretation, as regards paints and other formulated coatings, is inconsistent with its handling of other building materials. Section 162.4(c) (3) provides that building materials which are treated with a pesticide to protect the material itself and for which no pesticidal claims are made as protection of other surfaces or objects in the manufacture, sale, or distribution of the product are not considered pesticides, and therefore, are not subject to the registration requirements of amended FIFRA. After reconsideration, EPA has interpreted the definition of "pesticide" as applied to paints and other formulated coatings which are treated with fungicides, in a similar manner as all other building materials. Paints and other formulated coatings which are treated with fungicides to protect the dried coating itself and which are not intended for protection of other surfaces are not considered pesticides. However, paint products intended to be applied to a surface to kill mildew organisms and paint products formulated to kill or prevent the growth of mold in food processing plants, dairies and breweries are considered to be pesticides and will require registration in accordance with FIFRA, as amended. Promulgation of the regulations in this form, represents a continuation of the current policy.

The fungicide added to the paint or other formulated coating to protect the coating itself is a pesticide and is currently registered by the EPA. These products will continue to be so registered. Before the registration of any pesticide is approved by EPA the applicant must establish that his product under use conditions, satisfies all the requirements of the Act. The Agency accordingly, before registering such a fungicide for use as an additive in paints or other formulated coatings, must make the determination that the pesticide's composition is such as to warrant the claims made, it will be used without causing unreasonable adverse effects on man or the environment, and it otherwise complies with the requirements of the Act. The EPA is satisfied that a thorough review of the fungicide, with a view toward its end use, will protect man and the environment from unreasonable adverse effects.

Many questions have arisen concerning those statements of mildew resistance which will not subject a paint product to registration as a pesticide. The following label claims are acceptable, provided no additional claims implying protection of another surface are made elsewhere in the labeling or in advertising or other promotional material: "Mildew Resistant—treated with fungicide to protect the paint itself from growth of mildew"; "Mildew Resistant—This paint contains agents which inhibit the growth of mildew on the surface of this paint film"; "Dry coating of this paint mildew resistant"; "Dried paint film resists mold fungus"; "Dry enamel coating resists discoloration from mildew"; "Dried film resists stains by mold"; "A fungicide (or mold control ingredient, or mildew resisting component), has been incorporated in this product to make its dry film mildew resistant"; "Treated with fungicide (or specially formulated) to resist mildew growth on the paint film"; "Gives mildew-resistant coating"; "The mildew resistance of this outside house paint film makes it especially useful for use in high humidity areas"; "Contains * * * to protect the contents from spoilage"; "With fungicide—Resists film attack by mildew."

(b) A commenter suggested that a subsection be added to explicitly state that the term pesticide product does not encompass a substance or mixture of substances intended only for experimental use to determine its value for pesticidal purposes or its toxicity or other properties, where the user expects no benefit in pest control. Such an explicit statement is unnecessary: The concept is implicit in the definition of the term "pesticide" and the discussion of *Determination of Intent of Use* at Section 162.4(a). The concept is also in accord with the regulations recently published by EPA concerning experimental use permits, 40 CFR 172, 40 FR 18780, (April 30, 1975).

Section 162.5 *Pesticides Required to be Registered.* (1) Section 162.5(a) *Registration Requirement.* A new Section has been added to these regulations to set forth the statutory standard of Section 3(a) of amended FIFRA, regarding the requirement for registration of a pesticide product.

(2) Section 162.5(b)(1), [§ 162.5(a)], *Pesticides Exempt from Registration; Pesticides Transferred between Establishments.* (a) In accordance with section 3(b)(1) of FIFRA, as amended, this section sets forth the statutory exemption from the registration requirements for a pesticide transferred from one registered establishment to another registered establishment, operated by the same producer, solely for packaging at the second establishment or for use as a constituent part of another pesticide produced at the second establishment. Many commenters asked that the phrase "by the same producer" be deleted, or that "by or under contract" be added. Both of these suggestions conflict with the explicit language of the Act. Section 162.5(b)(1) is a verbatim rendition of the exemption created by section 3(b)(1) of the Act.

The Agency believes that much of the comment to this Section was generated by confusion as to the meaning of the term "operated by the same producer." Accordingly, the term has been defined at § 162.3(dd). An establishment operated by the same producer includes one owned by the registrant of the pesticide product and one operated under contract with the registrant of the pesticide product either to package the pesticide product or use the pesticide as a constituent part of another pesticide product, provided that the final pesticide product is registered by the transferor establishment. The proviso clause of this term is very important. It is not enough that a contract relationship exist between the parties. The transferor establishment must be the one that holds the registration of the final pesticide product. The Agency believes that Congress in its use of the term "operated by the same producer," has recognized the common business practice among registrants of contracting for the packaging or formulation of a pesticide product.

(b) Many questions have arisen concerning the scope of section 3(b)(1) of the Act and § 162.5(b)(1) of these regulations. A pesticide product, when transferred from one registered establishment to another registered establishment, operated by the same producer for the purposes indicated above, is exempt from the registration requirements of the Act. It must, however, be labeled so as to meet the other requirements of the Act. A sentence has been added to § 162.5(b)(1) listing the applicable Sections of the Act. This interpretation is consistent with the Agency interpretation of the similar provision in the Act prior to amendment. (section 4(e) 1947 FIFRA)

(2) Section 162.5(b)(3) [§ 162.5(c)] *Pesticides Exempt from Registration; Pesticides Transferred for Purposes of Disposal.* Pesticides shipped solely for purposes of disposal pursuant to Section 19 of the Act, Part 165 of the regulations, or an applicable Administrative order are exempt from the registration requirements of the Act. This provision, like the provision for pesticides transferred between establishments operated by the same producer, only relieves the pesticide product of the registration requirements of the Act. It must still be labeled so as to satisfy other requirements of the Act. A sentence has been added to § 162.5(b)(3) listing the applicable Sections of the Act.

(3) Section 162.5(b)(6) *Pesticides Exempt from Registration; Other Exemptions.* A new subsection (6) has been included to set forth the regulatory authority of section 25(b) of the Act, *Exemption of Pesticides.*

Section 162.6 *Registration Procedures.* All applications for new registration, amended registration, supplemental registration, and reregistration must comply with the requirements outlined at § 162.6.

(1) Section 162.6(a) *Applicant Requirements.* The applicant is responsible for the accuracy and completeness of all information submitted in connection with the application. If the Agency determines that an application is not sufficiently complete or that modification is necessary before a final decision on approval or denial of the application for registration, the applicant is notified and allowed a reasonable time within which to resubmit the application with deficiencies corrected. A commenter, in reliance on section 3(c)(6) of the Act, argued that an applicant should be granted only 30 days to resubmit his application if a notice of an incomplete application, pursuant to § 162.6(a)(5) is issued. Section 3(c)(6) of the Act grants an applicant only 30 days to correct deficiencies in his application if the Administrator informs him of his intent to deny the application for registration. A notice of an incomplete application, pursuant to § 162.6(a)(5), however, is not to be considered a denial of registration pursuant to section 3(c)(6) of the Act. Therefore, the Agency may grant the applicant who has received notice of an incomplete application a "reasonable time" within which to complete his application. In the event the applicant desires to have his application treated as having been denied, he may petition the Administrator for issuance of a notice of denial pursuant to section 3(c)(6) of the Act and § 162.7(e)(1) of these regulations.

(2) Section 162.6(b)(2) [§ 162.6(b)], *Application for New Registration.* (a) At the present time, before an application for registration will be approved, the Agency must accept the final printed labeling. Several commenters objected to this policy in general. The Agency's response to these comments is found below at the explanation of § 162.10(a)(6). A new § 162.6(b)(2)(i)(A) has been added to clarify that this policy will continue in effect as regards applications for new registration.

(b) Section 162.6(b)(2)(i)(C)(2) which indicates the factors the Agency considers in determining whether an ingredient is active or inert, appeared in the proposed regulations at § 162.3(c)(2). It has been transferred to this Section for purposes of organization.

(c) Section 162.6(b)(2)(i)(C)(3) provides that if the functional purpose of an ingredient is not reasonably apparent to the Agency, the Agency may request the applicant to state the purpose of the ingredient in the formulation. If any ingredient has no functional purpose, the Agency may determine that either the ingredient must be deleted from the formulation or that the application will be denied. Several commenters argued that this provision is without statutory authority. The mandate of the Environmental Protection Agency is to regulate the introduction of pesticides into the environment and prevent any unreasonable adverse effect on man or the environment. The intentional introduction of a contaminant into the environment, for which no functional benefit can be established, may be unreasonable and, unless the ingredient is deleted from the formulation, may be grounds for denial of the application for registration.

(d) Section 162.6(b)(2)(v), as proposed, has been deleted from these regulations because its substance is incorporated within § 162.6(b)(2)(i)(B). There were many comments concerning the data requirements of § 162.6(b)(2)(v), as proposed. These are discussed in the explanation of § 162.8(b)(3)(i), below.

(3) Section 162.6(b)(3) [§ 162.6(c)], *Application for Amended Registration*. (a) Section 162.6(b)(3)(i)(c) provides for marketing of a single registered product under multiple brand names. It had appeared in the proposed regulations at § 162.6(c)(5) but has been included here for purposes of organization. A commenter asked that allowance be made for the deletion of specific claims from a product label if by so doing no other changes are made necessary. Such a provision exists for the supplemental registration for distributor products, § 162.6(b)(4). An applicant for an amended registration can apply for a supplemental registration of distributor products at the same time as he applies for amended registration.

(b) Several commenters objected to the provision at § 162.6(b)(3)(ii) that final printed labeling must be accepted by the Agency before the application for amended registration will be approved. The Agency's response to this comment is found below at the explanation of § 162.10(a)(6).

(4) Section 162.6(b)(4) [§ 162.6(d)], *Application for Supplemental Registration of Distributor Products*. Several commenters argued that the regulations concerning supplemental registration are too stringent. They misunderstand the purpose of supplemental registration. The Agency merely intends to allow the marketing of a pesticide product under a distributor brand name. The distributor is not empowered to formulate, package or otherwise manufacture the pesticide product. The requirements for supplemental registration are designed to insure that the pesticide product is not adulterated.

(5) Section 162.6(b)(5) [§ 162.6(e)], *Application for Reregistration*. (a) Several commenters argued that it is impossible to complete by October 21, 1976 some of the long term testing required by these regulations for the reregistration of certain pesticide products. The Agency has always intended, in accordance with section 3(c)(2) of the Act, to permit sufficient time for applicants to obtain the additional information required by these regulations for the reregistration of certain pesticide products. Additional language has been added to § 162.6(b)(5)(ii) to clarify our procedures. This language provides that when these regulations require data for reregistration which cannot reasonably be anticipated to be compiled within the period of reregistration, the Administrator may classify and reregister a pesticide product for a reasonable period of time pending completion of the required testing, *provided* he determines that, based upon available data, the pesticide product otherwise satisfies the requirements of these regulations and the Act, and does not meet or exceed the criteria for risk set forth in § 162.11(a)(3). Such reregistration will be for a fixed term of less than five years, reasonable to allow development, submission and review of required data and will be nonrenewable. Where a pesticide product does not otherwise satisfy the requirements of the regulations, or where there is serious doubt as to the advisability of classifying and reregistering the pesticide product pending completion of the required testing, such action will not be taken. If at any time, sufficient evidence regarding unreasonable adverse effects from use of the pesticide comes to the attention of the Agency, proceedings to either change the classification of the product or cancel or suspend its use, as appropriate, will be initiated.

(b) Several commenters objected to the provision of the proposed regulations that final printed labeling must be accepted before the application for reregistration will be approved. The Agency's response to these comments is found below at the explanation of § 162.10(a)(6).

(c) Section 162.6(e)(3)(viii), as proposed required an applicant to submit any factual information, which had been obtained by him or come to his attention regarding adverse effects on man or the environment resulting from use of the pesticide. For purposes of organization this Section has been incorporated into § 162.8(a). A complete discussion of the comments received is found below at the explanation of that section.

(d) Prior to the effective date of these regulations, detailed procedures to be followed by applicants for reregistration of pesticide products shall be published in the Federal Register. This notice will address solicitation off applications for reregistration by the Administrator, the contents of the applications, and the Agency's intended policy regarding applications for amended registration and reregistration of distributor products. Registrants are asked to await these detailed procedures before contacting the Agency regarding reregistration of a product.

(6) Section 162.6(c) *Five Year Cancellation*. A new section has been added to the regulations to include procedures for the five year cancellation of pesticide products as required by section 6(a)(1) of the Act. Registration of a product for which notice of 5 year cancellation has issued will be continued in effect only upon the determination of the Administrator that the registration complies with all the requirements of the Act and the regulations which are promulgated thereunder and which are current at the time of renewal.

Section 162.7 *Disposition of Applications*. All applications for new registration, amended registration, supplemental registration, and reregistration will be processed as outlined at § 162.7.

(1) Section 162.7(b) *Notice of Receipt of Application for Registration*. A new § 162.7(b) has been included to clarify that the Agency will acknowledge receipt of all applications and return to the applicant a notification of the date of receipt of the application by the Agency. Section 162.6(b)(3), as proposed, had indicated that such procedures would be followed in the case of receipt of an application for new registration.

(2) Section 162.7(c) [§ 162.7(b)], *Time for Acting with Respect to Application*. A commenter asked that the phrase, "as expeditiously as possible," be deleted from this section and that another phrase be added to indicate that the applicant will be notified if review will take longer than 90 days. "As expeditiously as possible" is the language of the statute, section 3(c)(3). The Agency, in fact, intends to notify the applicant of the expected length of time necessary to process the application.

(3) Section 162.7(d)(1) [§ 162.7(c)(1)], *Approval of Registration. Criteria for Approval*. (a) Section 162.7(d)(1)(v) has been rewritten to more closely track the Food, Drug, and Cosmetic Act requirement for a tolerance or an exemption from a tolerance.

(b) For purposes of better organization, a new § 162.7(d)(1)(vi) has been added to incorporate the requirement of § 162.4(c) as proposed, which made registration of a product intended for use as a drug as well as a pesticide dependent on approval of the substance by the Food and Drug Administration. Several commenters argued that § 162.4(c), as proposed, should be deleted; and, because the Food and Drug Administration adequately regulates these products, pursuant to section 25(b)(1) of the Act, they should be exempt from the provisions of FIFRA, as amended. These commenters have failed to recognize the Congressional mandate to each Agency and the working relationship established between them. The language of § 162.7(d)(1)(vi) and § 162.4(c), as proposed, reflects the current Interagency Agreement between the Environmental Protection Agency and the Food and Drug Administration, 36 FR 24235 (December 22, 1971).

(4) Section 162.7(e) [§ 162.7(d)], *Denial of Registration*. This section, as proposed, granted an applicant the opportunity to petition the Administrator to withdraw his application. Implicit in the concept of a petition is the discretion of the Administrator to deny such a petition. Language has been added to § 162.7(e)(2)(ii) to explicitly state that the Administrator may in his discretion deny any petition for withdrawal and proceed to issue a notice of denial.

Section 162.8 *Data in Support of Registration & Classification*. (1) *Economic Impact*. Many commenters argued that the data requirements of these regulations will cause an unnecessary, adverse, and inflationary impact on the pesticide industry and agricultural sector of the economy.

On November 27, 1974 the President issued Executive Order 11821 (30 FR 41501) which requires each agency to certify that the inflationary impact of any major regulation has been evaluated. Accordingly, although the Agency believes that this regulation does not constitute "major action" within the meaning of the Executive Order, the following discussion summarizes EPA's consideration of the inflationary impact of these regulations and serves as the Agency's certification that such impact has been evaluated. The discussion focuses on the inflationary impact of the data requirements necessary to comply with these regulations because the Agency has determined that such costs are the most significant potential costs which may be caused by the implementation of these standards for registration pursuant to the amended FIFRA.

The data requirements for registration of a pesticide have been increasing slowly and steadily over the past 25 years. These regulations, and the referenced Registration Guidelines, for the most part catalogue the specific requirements which have been in effect for the past several years. The regulations reduce uncertainty by fully informing the applicant of the data necessary to support an application for registration. EPA believes this will increase the efficiency of pesticide research and development and result in a shorter average duration of time between submittal of an application for registration and a decision regarding the application by the Agency.

The data requirements for reregistration will not pose a significant economic burden on many pesticide registrants. The data requirements have been tailored to address the particular concerns regarding pesticides already registered by the Agency in light of data previously submitted to the Agency in support of the initial registration and the pesticide's use history. The data requirements for reregistration can generally be satisfied with tests on the active ingredient. This fact greatly reduces the burden on many pesticide registrants because an evaluation of one active ingredient will satisfy the requirements of many formulated pesticide products. In addition, if the data have previously been submitted to the Agency, as for example in support of a tolerance, and they meet the intent and reliability standards of the Registration Guidelines, no new submission will be required. Moreover, § 162.6(b)(5)(ii) provides that if data are required which cannot reasonably be anticipated to be compiled within the period for reregistration, the Administrator may, in his discretion, classify and reregister the pesticide product for a reasonable period of time pending completion of the required testing, provided he determines that the pesticide does not meet or exceed the criteria for risk set forth in § 162.11(a)(3) and that the pesticide product otherwise satisfies the requirements of these regulations and the Act.

The data requirements for new registration were arrived at by considering the data requirements currently in effect and evaluating additional risks which those data requirements had not considered. The cost of the incremental data represented by these regulations is minimal compared to the total pesticide development cost. The increased safety represented by the expanded data base more than offsets the cost of the required tests. It is expected that the emphasis of these regulations on human and environmental health will induce a reorientation in the priorities of many companies. By closely scrutinizing environmental and health effects earlier in the development of a pesticide, more pesticides will achieve full registration within a lesser amount of time. Such increased efficiency should reduce the risks of the pesticide industry and their costs due to failure of a pesticide to secure full registration.

In enacting the 1972 FIFRA, Congress recognized that thorough data requirements are necessary to support an application for registration and further recognized that the cost of securing these data is an added burden to the pesticide industry. It incorporated section 3(c)(1)(D) into the Act to compensate the party who produces the data and, in effect, extended the proprietary rights of the producer beyond the term allowed by present patent law. The existence of this provision reduces the individual economic impact of these data requirements and clearly indicates that Congress intended the economic burden of data requirements to be shared by groups of registrants whose registrations are supported by such data rather than be the cause of an inadequate data evaluation.

(2) Section 162.8(a) *General.* (a) Several commenters suggested that § 162.8 be deleted from the regulations and placed in the Registration Guidelines. The purpose of the Registration Guidelines is to specify the kinds of information which will be required to support the registration of a pesticide. Section 162.8 of these regulations does not preempt the Guidelines. It is included in these regulations to delineate the major data requirements of the Registration Guidelines and direct the potential applicant or other interested party to the Guidelines. Many of the data requirements set forth in Section 162.8 are conditional and will only be required for those products which meet the indicated conditions. The applicant is referred to the Registration Guidelines to determine the detailed data which are required to support a specific application for registration. The Guidelines also specify acceptable test methods and protocols to be followed in accumulating the data.

(b) Several commenters argued that the data requirements of these regulations and the Registration Guidelines, even taking into account the conditional nature of many of the data requirements, are inapplicable to certain pesticides or pesticide products and are not necessary for a determination of whether such pesticide product will generally cause unreasonable adverse effects on man or the environment. The Agency has attempted to consider all pesticides in developing the data requirements. The Agency recognizes, however, that these regulations and the Registration Guidelines may not have taken into account all relevant factors for all pesticides. Accordingly, the proposed regulations at § 162.8(b)(1)(i) had provided for a waiver of data requirements upon petition of the applicant. That provision has been modified and a new § 162.8(a)(3) has been included to specify the detailed procedures and basic standard to be applied by EPA for waiver of a data requirement specified in these regulations or the Registration Guidelines. Waiver of a data requirement is permissible only if the Administrator determines (1) that the composition, degradability, proposed patterns of use or other chemical or physical properties of the pesticide, relating to an evaluation of the effects on man or the environment, are fundamentally different from the properties considered by the Agency in establishing the data requirements of these regulations or the Registration Guidelines, and therefore (2) that the data are not necessary in order for him to determine whether such specific pesticide or product will generally cause unreasonable adverse effects on man or the environment. Generally, an applicant must initiate the process and submit a written statement setting forth his reasons for requesting a waiver from a data requirement. In the case of reregistration, however, the Administrator may initiate the waiver of a data requirement by so indicating in his solicitation of applications for reregistration. The Administrator will make a written finding with respect to waiver of a data requirement. In the case of the approval of any application for which notice of application was published in the FEDERAL REGISTER pursuant to § 162.6(b)(6), if the Administrator determines to waive a data requirement, the notice of approval issued pursuant to § 162.7(d)(2) shall list any data requirement which has been waived and briefly state the basis for such waiver. In the case of waiver of a data requirement initiated by the Administrator in the solicitation of applications for reregistration, the notice of solicitation shall list any data that have been waived and briefly state the basis for such waiver. Notice to the public of the waiver of a data requirement satisfies EPA's responsibility under the Act, these regulations, and the general principles of Administrative Law to set forth the rationale for any departure from its regulations.

(c) A commenter requested that EPA require the applicant for both new registration and reregistration to submit all relevant information available from scientific literature and other sources on the potential adverse effects of a pesticide. In the proposed regulations at § 162.6(e)(3)(viii), this provision by its terms applied only to reregistration, although the Agency intended that the requirement apply to all registrations. Moreover, we believe that this provision more properly belongs in § 162.8. Accordingly, § 162.6(e)

(3) (viii), as proposed, has been deleted and a new § 162.8(a)(4) has been included to specifically impose upon the applicant the responsibility to submit any factual information which has been obtained by him or come to his attention regarding the adverse effects of his pesticide on man or the environment. Such information may include, but is not limited to, published or unpublished laboratory studies and accident experience.

Several commenters objected to the policy of this section. They argued that the applicant should only be responsible for submitting his own data and not data found in the general literature. Section 6(a)(2) of the Act and § 162.8(a) of these regulations imposes on the registrant the affirmative duty to report any additional factual information regarding adverse effects on man or the environment of the pesticide. EPA interprets report of scientific findings contained in the general literature as within that duty. This same affirmative duty is imposed upon the applicant for registration as well. The burden for establishing the safety of a product is on the applicant at all times. He must convince the Administrator, in part, that the pesticide will perform its intended function and that it will be used without unreasonable adverse effects on the environment before the initial decision may be made to register the product. This duty falls on the applicant and registrant because they are in the better position to monitor the literature as regards a particular pesticide.

Many commenters expressed support for the Section as proposed, and asked that penalties, as for example immediate cancellation or seizure, be established for the withholding of information. The civil and criminal penalties arising pursuant to sections 12(a)(2)(N) and 14 of the Act are the statutory remedies for achieving compliance with these regulations.

(d) Both § 162.8(b)(1) (ii) and (iii), as proposed, have been deleted from these final regulations in order to avoid redundancy. The substance of § 162.8(b)(1)(ii) is repeated at § 162.8(d). The substance of § 162.8(b)(1)(iii) is repeated at §162.8(b)(4).

(3) Section 162.8(b)(2) *Data Requirements for New Registration. Efficacy.* (a) A commenter suggested that § 162.8(b)(2)(i) be amended to require only data necessary to support the label claims for effective dosage and dosage range. This suggestion must be rejected because without data to support the minimum effective dosage and effective dosage range, the Agency can not be sure that the correct dosage and dosage range have been assigned for the pesticide product use(s).

(b) In response to comment, a new § 162.8(b)(2)(iv) has been included to delineate the Registration Guidelines requirement for data, when appropriate, to support the measurement of toxic effects to plants or animals that are host to the pests. This information, when relevant, has customarily been required of applicants for registration.

(c) Section 162.8(b)(2)(iv), as proposed, required an evaluation of the chemical and physical compatibilities of components of formulated pesticides. It has been deleted from these regulations because it was not a general requirement applicable to the majority of applications for registration. The Registration Guidelines contain this data requirement and indicate, with specificity, the conditions under which such an evaluation is required.

(4) Section 162.8(b)(3)(i) *Data requirements for New Registration. General Chemistry.* (a) Some commenters argued that the general chemistry data required by § 162.8(b)(3)(i) would not be available to formulators of a pesticide product. A formulator may rely on the data submitted by the basic manufacturer of the pesticide provided he complies with the procedures established pursuant to section 3(c)(1)(D) of the Act.

(b) Sections 162.8(b)(3)(i)(A)(1) and 162.8(b)(3)(i)(B)(1) require the applicant to submit data relative to the complete general chemistry of the pesticide and the pesticide formulation, including the complete composition of the technical chemical, and the chemical names and percentages of all impurities. A commenter argued that these Sections are too stringent and that the applicant should only be required to submit information relative to the composition of the technical chemical, including the percentages of all impurities and the chemical name of known impurities. The Agency recognizes that the best scientific methodology may leave a percentage of impurity unidentified. As determined by the Administrator, on a case by case basis, an application for registration may be approved where a very small percentage of impurity is unidentified, if the Administrator determines that the best available methodology has been utilized to evaluate the pesticide and the pesticide formulation, and that use of the pesticide will not generally cause unreasonable adverse effects on man or the environment.

(c) Several commenters argued that EPA has no authority to require data relative to the basic manufacturing process of the technical chemical, § 162.8(b)(3)(i)(A)(2), or of the pesticide formulation, § 162.8(b)(3)(i)(B)(2). They argued that these provisions are an attempt by the Agency to regulate quality control. Section 3(c)(5) of the Act provides that the Administrator shall register a pesticide if he determines, in part, that its composition is such as to warrant the proposed claims for it and if he is satisfied that it will perform its intended function without unreasonable adverse effects on man or the environment. The Agency is required by statute to determine the exact composition of the pesticide and pesticide formulation. Contaminants which will cause unreasonable adverse effects on the environment may unintentionally be introduced into the pesticide or the pesticide formulation by a modification of the manufacturing process. The data specified at § 162.8(b)(3)(i)(A)(2) and § 162.8(b)(3)(i)(B)(2) have been required by EPA prior to the promulgation of these regulations, pursuant to the authority of the 1947 FIFRA. Nothing in the legislative history or language of the amended Act indicates a modification of that regulatory authority. Such data, moreover, are required before issuance of an experimental use permit, pursuant to section 5 of the Act, for use of an unregistered pesticide product. 40 CFR 172.4(b)(3)(ii), 40 FR 18780, 18784 (April 30, 1975).

(d) Section 162.8(b)(3)(i)(A)(3) requires data on the purity of starting and intermediate materials used in the manufacturing process. Several commenters suggested test methodology for securing these data. These comments have been considered in developing the Registration Guidelines.

(5) Section 162.8(b)(3)(ii) *Data Requirements for New Registration. Environmental Chemistry.* In response to comment, this Section has been substantially rewritten to clarify the conditions under which specific data relative to the environmental chemistry of the pesticide will be required. Data on field stability, persistence, degradation, accumulation, and mobility are generally required only if the pesticide is intended for outdoor application. Information to support the "safe disposal" of the pesticide formulation and pesticide container, as defined at 40 CFR 165.1(s), is generally required of all pesticide products. The applicant is referred to the Registration Guidelines for the detailed conditions for the data requirements and for acceptable test methodology and protocols.

(6) Section 162.8(b)(4) *Data Requirements for New Registration. Product Hazard.* (a) In response to comment, § 162.8(b)(4) has been substantially rewritten to clarify the conditions under which specific data relative to product hazard will be required and to refer the applicant to the Registration Guidelines for the detailed conditions for such testing. The Guidelines specify, in addition, whether the data are to be derived from tests on the active ingredient(s), the pesticide formulation, or the major metabolite(s) degredation and/or reaction product(s).

As is discussed below, no mutagenic requirement normally exists for reregistration. For purposes of new registration, the applicant is referred to the Guidelines and Appendices thereto for the conditions under which such testing will be required and for the protocols to be followed. The Guidelines have just been published as proposed and the Agency especially welcomes comment concerning this data requirement.

(b) In response to comment, § 162.8(b)(4)(i)(C) has been amended to require, instead of merely diagnostic and antidotal information, diagnostic, first aid, palliative, and/or antidotal information. Commenters correctly pointed out that the language of the proposed regulations was too restrictive since there is no known effective antidote for the majority of pesticide products, following sufficient exposure.

(7) Section 162.8(c) *Data Requirements for Reregistration*. (a) Several commenters argued that the data requirements for reregistration are too lenient and that they should be identical to the data requirements for new registration. Other commenters argued that the data requirements for reregistration are too burdensome. The data requirements for reregistration have been tailored to address the particular concerns regarding pesticides already registered by the Agency.

We have indicated those use patterns, chemical structures and exposure levels for which a determination on any potential risks to the health and safety of man or the environment is required prior to registration. In light of the use history and prior registration of these pesticides, we have determined that evaluation of the data indicated at § 162.8(c) is necessary and sufficient for the determination of whether or not reregistration of the pesticide product will cause an unreasonable adverse effect on man or the environment. EPA realizes that full compliance with the data requirements imposed on new registrations would be desirable for reregistration as well. By October, 1976, however, EPA must reregister in excess of 30,000 pesticide products. It would be administratively impossible to require all of these products to satisfy the data requirements for new registration. Five year renewals of registration, however, will be processed on a staggered basis; it is at this junction that the then current data requirements for new registration will apply to all products previously registered by the Agency.

Registrants of pesticide products that come within the criteria specified at § 162.8(c), will be required to submit such additional data prior to reregistration unless (1) such data have previously been submitted to the Agency and the data meet the intent and reliability standards specified in these regulations and the Registration Guidelines, or (2) the Administrator determines, pursuant to section 3(c)(2) of the Act and § 162.6(b)(5)(ii) of these regulations, that the data cannot reasonably be compiled within the time for reregistration, that the pesticide otherwise satisfies the requirements of the Act and these regulations, and that the pesticide does not meet or exceed the criteria for risk set forth in § 162.11(a)(3). In this latter case, the Administrator may classify and reregister the pesticide for a reasonable period of time pending completion of the required testing. The reader is referred to the discussion of § 162.6(b)(5)(ii), above.

(b) Section 162.8(c)(3)(i) has been modified in response to comment to alter the conditions under which a teratogenic evaluation of a pesticide will be required for reregistration. The proposed regulation has required the testing "if the pesticide use results in significant exposure to women in residences enclosed working spaces or their immediate vicinity." The Agency has determined that this data requirement was too restrictive. The place of exposure to a potentially hazardous pesticide is not as important as the fact of exposure. Accordingly, a teratogenic evaluation of the active ingredient in a mammalian test system is required as a condition of registration "if the pesticide may reasonably be expected to result in exposure to female humans."

(c) Sections 162.8(c)(ii), (iii) and (iv) specify, respectively, that oncogenic, chronic feeding, and reproductive studies of the active ingredient(s) will be required for pesticides which need a tolerance or an exemption from the requirements to obtain a tolerance. Several commenters urged the Agency to reconsider these sections, noting that this requirement represents a change from the existing policy of requiring only subacute feeding studies in support of petitions for tolerances for negligible residues. Section 40 CFR 180.1(1) defines the term "negligible residue" to mean "any amount of a pesticide chemical remaining in or on a raw agricultural commodity or group of raw agricultural commodities that would result in a daily intake regarded as *toxicologically insignificant* on the basis of scientific judgment of adequate safety data. Ordinarily this will add to the diet an amount which will be less than 1/2000th of the amount that has been demonstrated to have no effect from feeding studies on the most sensitive animal species tested. Such toxicity studies shall usually include *at least* 90-day feeding studies in two species of mammals." (Emphasis added) In the past, the Agency has frequently considered 90-day feeding studies to be sufficient to support the petition for the establishment of a tolerance for negligible residues. However, the Agency has determined that the results of such 90-day studies cannot always establish that a residue is toxicologically insignificant. A 90-day time period will generally be inadequate to confidently predict the effects from life time exposure. Human exposure to some chemicals such as carcinogens can have significant chronic effects even at very low levels. Moreover, as explained in the recent decision of the Administrator suspending the registrations of pesticides containing Aldrin and Dieldrin and in the United States Court of Appeals for the District of Columbia Circuit opinion affirming that decision, although no effect may theoretically exist, in cancer testing it is often impossible to determine such a safe level. Furthermore, the Agency is aware of no data to justify waiving of the requirement for chronic feeding and reproductive studies for those pesticides which leave residues in food at very low levels. An explanation of the waiver of data requirement provision appears at the Preamble discussion of § 162.8(a)(3), above.

(d) Section 162.8(c)(3)(iii), as proposed, has been deleted from these final regulations. The Agency is currently re-evaluating existing requirements for mutagenicity testing and protocols as part of the development of the Guidelines. Until this review is completed, additional mutagenic testing will not be required for purposes of reregistration, except where the Agency determines that, for an individual pesticide or pesticide product, mutagenic evaluation should be completed as part of the reregistration determination pursuant to § 162.8(d).

(8) Section 162.8(d) *Additional Data*. This section has been rewritten to emphasize and clarify for the registrant his duty to submit any additional data requested by the Administrator. In addition, a new paragraph has been included to state in the regulations the registrant's duty pursuant to section 6(a)(2) of the Act, to immediately submit to the Agency any factual information regarding adverse effects on man or the environment of the pesticide. Such information includes published or unpublished laboratory studies, whether or not contained in the general literature, and accident experience. These requirements recognize that the registrant is in the best position to monitor such sources with respect to a particular pesticide, and that additional data may be required where it is appropriate in order to evaluate efficacy or hazard. Moreover, the Agency will also take into account evidence submitted by other parties.

Section 162.10 *Labeling Requirements*. Section 162.10 implements the new labeling requirements of FIFRA, as amended, and attempts to improve the communicative value of labels and labeling in general. Section 12(a)(2)(G) of the Act makes it unlawful for a person to use any registered pesticide in a manner inconsistent with its labeling. Several commenters suggested that the phrase "use inconsistent with the labeling" be defined in these regulations. Such a task would be impractical because the phrase has a different meaning in each of several regulatory contents. In order to respond to specific questions as they arise and keep the public informed of Agency policy in this regard, EPA has instituted a series of Pesticide Enforcement Policy Statements to provide public notice of instances in which deviations from the precise language of a product label will not subject the user to enforcement liability. See 40 FR 19526 (May 5, 1975).

Many changes in labeling requirements were recommended by participants in the First National Symposium on Pesticide Labeling, June 3–4, 1974. Most of these suggestions have been incorporated into these regulations, as for example the format changes and grouping of use and warning and precautionary statements. Adoption of some of the recommendations will be deferred until after completion of the reregistration effort because of the complexity of the provisions and the far reaching effects which are to be anticipated. Included within this class are suggestions that nontechnical homeowner pesticide labels be accepted and that master labels for use directions on an active ingredient basis be adopted. Officials of the EPA will be conducting Regional Label Symposia to secure public participation in the development of forthcoming standards for pesticide labels.

(1) Section 162.10(a) (2) *Prominence and Legibility*. Section 162.10(a) (2) (ii) (A) provides that all required label texts must be set in 6-point or larger type. Several commenters argued that this requirement is overly burdensome and that it does not provide latitude for small products. The type size requirement is mandatory because it improves the communicative value of the label text. A manufacturer of a small pesticide product, in accordance with § 162.10(a) (4) (i), is encouraged to securely attach labeling to the immediate container of a pesticide product. Such labeling must reasonably be expected to remain affixed to the immediate container during the foreseeable conditions and period of use.

(2) Section 162.10(a) (3) *Language to be Used*. All label or labeling text must appear in the English language. The proposed regulations had provided, in addition, that when text in another language is considered necessary, the complete label text must appear in both languages. Several commenters argued that space limitations do not always permit complete dual language labeling. This requirement has been deleted from these final regulations. The Agency may determine that for a particular pesticide additional text in another language is required to protect the public. In that case, depending on the nature of the hazard of the pesticide, the complete label text may be required in both languages, or the phrase "If you cannot read English do not use this product until properly instructed." In the language of the anticipated user of the pesticide may be accepted.

(3) Section 162.10(a) (4) *Placement of Label*. (a) Several questions arose concerning § 162.10(a) (4) (i), as proposed. These regulations are intended to continue EPA's present practice of requiring a full user-label on the outside wrapper or container of a retail package, if the immediate container of the pesticide is enclosed within a wrapper or outside container through which the label of the immediate container cannot be clearly read. The language of this section has been rewritten to clarify the Agency's intended practice.

(b) Several commenters argued that the requirements at § 162.10(a) (4) (ii) for labeling of tank cars and other bulk containers, as proposed, were inconsistent with the requirements imposed by the Department of Transportation on these same containers. The Environmental Protection Agency is concerned with securing uniformity of regulation. Accordingly, this section has been rewritten so that the EPA regulations concerning transportation of pesticides are consistent with the regulations of the Department of Transportation concerning transportation of hazardous materials. A separate subsection has been included to specify the labeling required for pesticides stored in bulk containers.

(4) Section 162.10(a) (5) *False or Misleading Statements*. (a) Section 162.10(a) (5) provides that a pesticide is misbranded if its labeling is false or misleading in any particular, including both pesticidal and non-pesticidal claims. The specific reference to non-pesticidal claims had appeared in the proposed regulations at § 162.4(b) (5). Commenters argued that the Agency lacks statutory authority over the non-pesticidal claims of a pesticide product. Our response to this comment is found above in the discussion of § 162.4(b).

(b) Section 162.10(a) (5) (v) provides that any statement which directly or indirectly implies that the pesticide or device is recommended or endorsed by any Agency of the Federal government is misbranding within the meaning of § 2(q) (1) (A) of the Act. A commenter correctly pointed out that under certain conditions of sale pesticides are required to meet government specifications. A registrant may, in these circumstances, indicate that his product conforms to an Agency specification. He may not, however, imply that his product is recommended or endorsed by the Agency.

(c) Several commenters objected to the language of § 162.10(a) (5) (vi). They argued that a *per se* rulemaking a trademark which suggests one or more, but not all, principal active ingredients in a pesticide a false or misleading statement is not in accordance with accepted principles of trademark law. In determining whether or not to register a trademark, the Patent Office makes no determination of its legality under the FIFRA, as amended. Therefore, registration of a trademark cannot be accepted as evidence that a name is legal under the Act. If a name is false or misleading, it is a violation of FIFRA, as amended, whether or not it has been registered as a trademark.

(d) Several commenters were confused by § 162.10(a) (5) (x), as proposed. It has been rewritten to give examples of non-numerical and/or comparative statements on the safety of a pesticide product which the Agency considers to be false and misleading, within the meaning of section 2(q) (1) (A) of the Act.

(5) Section 162.10(a) (6) *Final Printed Labeling*. At the present time, before a new registration will be approved, the Agency requires acceptance of final printed labeling. These regulations continue this policy with regard to approval of applications for new registration, § 162.6(b) (2), and extend the policy to cover approval of applications for amended registration, § 162.6(b) (3), and approval of applications for registration, § 162.6(b) (5). Commenters generally objected to this policy. They argued that the practice is burdensome and laden with delay. Some commenters made a distinction between applications for new registration and applications for amended or reregistration, arguing that though acceptance of final printed labeling is appropriate before approval of an application for new registration, it is not necessary before approval of an application for amended or reregistration. The Agency can make no such distinction in the case of label review since section 3(c) (5) (B) of the Act specifically requires the Administrator to determine that labeling is in compliance with the Act before registration of a product. Review of the final printed labeling is, therefore, necessary before any application for registration is approved. EPA will review the final printed labeling as quickly as possible. If it is identical to the conditionally accepted labeling, no appreciable delay in approval of the application should occur.

(6) Section 162.10(g) (3) *Names to be Used in Ingredient Statement*. A commenter objected to the language of § 162.10(g) (3) as proposed, arguing that common names are assigned to active ingredients by special national and international organizations such as the American Standards Association and the International Standards Organization, and that the Agency should merely accept these names. Section 25(c) (6) of the Act authorizes the Administrator, after notice and opportunity for hearing, to determine and establish suitable names to be used in the ingredient statement. Accordingly, the Agency will compile and promulgate by regulation a list of acceptable common names. Interested parties will be afforded opportunity to comment before adoption of these names, and consideration will be given to those names assigned by the special national and international organizations.

(7) Section 162.10(g) (4) *Statement of Percentages*. A commenter suggested that if the use(s) of the pesticide is expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation should be required in the ingredient statement because unless the precise total weight per unit of volume is known, it is impossible to determine the amount of product to use. The Agency agrees that this information is necessary in such instances, and has included such a provision in § 162.10(g) (4).

(8) Section 162.10(g) (6) *Deterioration*. (a) Section 162.10(g) (6) (i), as proposed, required the statement "This product is subject to deterioration. Not for sale or use after [date]" on any pesticide product subject to significant deterioration. Many commenters objected to the required label statement—"This product is subject to deterioration." They argued that it has unnecessary negative connotations since all products are subject to some deterioration, and that such a statement is not required of products, such as film and drugs, which also may deteriorate over time. They also maintained that the phrase "Not for sale or use after [date]" will adequately protect the public. The Agency agrees that a statement of expiration time will adequately protect the public and accordingly these regulations have deleted the requirement for the label statement "This product is subject to deterioration."

(b) Section 162.10(g) (6) (ii) provides that the pesticide product must meet all label claims up to the expiration time indicated on the label. Several commenters argued that the responsibility should fall on the consignee of the pesticide product to remove the product from the channels of trade after the date of expiration has passed. A registrant may establish by contract or custom a mutually beneficial working relationship with his consignee. The legal responsibility for sale of the pesticide product remains, however, with both the manufacturer and the distributor unless there is a guarantee pursuant to section 12(b) (1) of the Act and § 162.12 of these regulations.

(9) Section 162.10(g) (7) *Inert Ingredients.* (a) Several commenters argued that the Administrator has no statutory authority to require that the name of an inert ingredient appear on labeling even when the Administrator determines that an ingredient may pose a hazard to man or the environment and that the user should be given notice of the hazard. Such a position contradicts the Administrator's basic obligation under the amended FIFRA of determining the risks which may be posed by a pesticide and imposing the necessary regulatory requirement to adequately control an unreasonable risk. Depending on the risk involved, the Administrator is authorized by the amended FIFRA to: (1) deny registration or cancel an existing registration, (2) classify the pesticide for restricted use, or (3) require specific label statements. Accordingly, the regulations provide that the Administrator may require the listing of inert ingredients on labeling where the ingredients may pose a hazard. This requirement does not affect the Administrator's authority to require testing of inerts or to take other regulatory action if the label statement does not protect against the hazard.

(b) Other commenters suggested that all inert ingredients be listed in the ingredient statement or, in the alternative, that those inert ingredients known to be hazardous be listed in the ingredient statement and an open file of all the inert ingredients of each pesticide product be maintained for public inspection. FIFRA, as amended, does not require the name of all inert ingredients to be contained in the label ingredient statement and therefore, barring a determination of hazard to man or the environment, the name of the inert ingredient(s) of a pesticide formulation will not be required in the label ingredient statement. In the event of an accident, it often is imperative for the attending physician to identify the ingredients of the pesticide formulation so that appropriate medical treatment can be provided. EPA is considering institution of a toll free telephone service to provide such information in the case of a medical emergency.

(10) Section 162.10(h) *Warnings and Precautionary Statements.* (a) The comments indicated much confusion regarding placement on the label of the warnings and precautionary statements required by this section. There are two general categories of warnings and precautionary statements—those required to appear on the front panel and those which may appear elsewhere. The human hazard signal word, § 162.10(h) (1), child hazard warning, § 162.10(h) (1) (ii), and in certain instances statements of practical treatment, § 162.10(h) (1) (iii), must all appear on the front panel. Statements regarding hazard to humans and domestic animals, § 162.10(h) (2) (i), environmental hazard, § 162.10(h) (2) (ii), and physical or chemical hazards, § 162.10(h) (2) (iii), are required to appear under an appropriate subheading elsewhere on the label.

(b) Many commenters suggested changes in several indicators for determining the toxicity category of a pesticide as set forth in the table at § 162.10 (h) (1).

(i) *Inhalation* LC_{50}. The proposed regulations provided that the inhalation LC_{50} of a pesticide could be expressed, depending on the formulation of the product, in terms of milligrams per liter for dust or mist or parts per million of medium for gas or vapors. A commenter argued that use of these two scales is confusing, and that the Agency could easily convert from one scale to the other. To clarify this Section, the scale of toxicity on the basis of parts per million of medium has been deleted.

(ii) The numerical criteria for assigning a toxicity category on the basis of an inhalation LC_{50} have been relaxed in these final regulations by a factor of ten. On the basis of a review of the use history and available scientific literature, EPA has determined that the proposed regulations were overly stringent and that the public and the environment will be protected under the regulations as now published. Individuals exposed to pesticides meeting the proposed criteria would very likely have experienced dermally toxic effects more significant than the inhalation effects.

(2) *Eye effects*—Several commenters correctly pointed out that pursuant to the regulations as proposed substances which are corrosive to the eye were not explicitly placed into Toxicity Category I. This was an error. The Agency intended to continue its current practices regarding assignment of a toxicity category on the basis of eye effect. Language to this effect has accordingly been included. Other commenters proposed schemes which used conjunctivitis and iritis as indicators of toxicity for eye effects. The Agency interprets these conditions as within the generic term "irritation," which is used in these regulations.

(3) *Skin effects*—As with the toxicity categories for eye effects, the proposed regulations regarding skin effects did not clearly indicate that substances corrosive to the skin fall into Toxicity Category I. Language to that effect has been included in these final regulations. In addition, the toxicity category into which a pesticide will fall on the basis of skin effects has been relaxed because the Agency has determined that the more stringent criteria contained in the proposed regulations are not necessary to protect against anticipated adverse skin effects from pesticide use.

(c) Several commenters asked that the provision at § 162.10(h) (1) (i) (D), requiring the human hazard signal word "Caution" on all Toxicity Category IV pesticides, be deleted. They correctly pointed out that § 162.10(h) (2) (i) (B) provides that no precautionary statements are required for Category IV pesticides. There is no contradiction between these two sections. A precautionary statement is not a human hazard signal word. It is the current Agency practice to require the human hazard signal word "Caution" on all Category IV pesticides. The nature of pesticides, in general, is such that all must be handled with caution.

(d) Commenters argued that the precautionary statements outlined in § 162.10(h) (2) (i), (ii), and (iii) are confusing and incomplete. These Sections are intended merely to be illustrative of precautionary statements which may be accepted. The statements should be modified to reflect the specific hazards of a particular pesticide product.

(11) Section 162.10(i) *Directions for Use.* Section 162.10(i) (2) (x) has been amended to specify with greater clarity statements which may be required in the Directions for Use of products classified for restricted use. Section 162.10(i) (2) (x) (D) provides that the category or categories of a certified applicator to whom use is restricted must be included in the Directions for Use unless the Agency determines that the product may be used by any certified applicator. Section 162.10(i) (2) (x) (E) provides that a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, will be required in the Directions for Use, unless the Agency determines that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(12) Section 162.10(j) *Statement of Use Classification.* Section 162.10(j) requires that by October 22, 1976 all pesticide products must bear the appropriate statements of use classification as described in paragraphs (1) and (2) of that section, General Use Classification and Restricted Use Classification, respectively.

(a) Section 162.10(j) (2) provides that, if use of a pesticide is restricted to a certified applicator, the following statement is required on the product label: "For retail sale to and application only by Certified Applicators or persons under their direct supervision." Many commenters argued that this provision is without statutory authority. The legislative history of amended FIFRA clearly indicates that Congress contemplated that certain pesticides should be removed from the general public domain, for use only by certified applicators. In the presentation of the bill on the Senate floor it was explained: "In order to provide for a more finely tuned control of pesticide use, the bill provides further for the division of pesticides into general use pesticides and restricted use pesticides * * * * The sale of restricted use pesticides could be limited to certified applicators who had proven their ability to use them properly and who face loss of certification if they use them contrary to regulation." 118 CONG. REC. S15894 (September 26, 1972). Moveover, the Agency has determined that many accidents occur because of improper transportation and storage practices. The restriction on sale of these restricted use pesticides is designed to minimize the risks from their use. A certified applicator will have established his competence in proper handling, transportation and storage techniques.

Many of the objections raised to this Section were the result of misunderstandings. The Agency does not intend to preclude an individual who is properly certified from following the common practice of having a third party, who is propertly instructed as to the correct manner of storing, handling and transporting the pesticide and who is properly supervised by the certified applicator, purchase the restricted use pesticide on his behalf. Such activity would be considered to be within the direct supervision of the certified applicator. The certified applicator's spouse, employee or tenant may be within this class of competent person. Moreover, the regulations do not require that a distributor be certified in order to purchase a restricted use pesticide from the manufacturer. In order to clarify this position, the phrase "retail sale" has been substituted for the word "sale," which had appeared in the regulations as proposed.

Any product classified for restricted use may be limited to use by or under the direct supervision of a certified applicator. Moreover, pursuant to section 3(d)(1)(C)(ii) of the Act and § 162.11(c)(5), of these regulations, the Administrator may additionally or alternatively impose other regulatory restrictions. Several commenters argued that the regulations as proposed did not provide for appropriate labeling in the case a pesticide is only restricted pursuant to any other regulatory restriction. The language of § 162.10(j)(2)(i)(B) has accordingly been amended to clarify that the requirement for a label statement restricting sale and application of a pesticide to certified applicators, or persons under their direct supervision, applies only to pesticides whose registration so restricts them. If any other regulatory restriction alone is imposed on the pesticide's use, the Administrator will define the appropriate labeling for the terms of restriction.

Several commenters argued that it is overly burdensome to impose this restriction on sale of restricted use pesticides by October, 1976. They believe that most applicators will not be certified by that date. Extensive commitments have been and are continuing to be made to the institution of a fully operative certification program. If by 1976, it is evident that an insufficient number of pesticide applicators have been certified, consideration will be given to amending these regulations.

(b) The proposed regulations had provided that any pesticide for which some uses are classified for general use and others for restricted use must be separately labeled in accordance with specified labeling standards, and marketed as separate products with different registration numbers, one for the general use(s) and the other for the restricted use(s). Several commenters argued that this provision is beyond the statutory authority of the Agency. Section 3(d)(1)(A) of the Act specifically authorizes the Administrator to require separate packaging and labeling to distinguish the restricted and the general uses of a pesticide.

The purpose of this section is to prevent pesticide misuse and accidents in the future. In order for the provisions of § 162.10(j)(2), discussed above, to have any practical effect, products must be separately labeled and marketed according to use classification. Commenters argued that the requirement of separate labeling will encourage deletion from product labels of specialized or minor crop uses. EPA is committed to support of minor and specialty crop uses and is encouraging individual States to register pesticides for these uses pursuant to section 24(c) of the Act and the regulations thereunder.

Several commenters argued that although it is reasonable for restricted use(s) not to appear on the general use label, general use(s) should be permitted on the restricted use label. The Agency recognizes that a certified applicator is well qualified to use a pesticide for both its restricted and general uses. Therefore, a provision has been included in § 162.10(j) to permit both the general and restricted uses of a pesticide to appear on the label of a restricted use product. Such products are subject to all provisions of § 162.10(j)(2). It would be a use inconsistent with the labeling for an individual, other than a certified applicator or someone under his direct supervision, to use such a product even for its general use(s).

(c) Several commenters suggested changing the placement and wording of the classification statement for general use products. The proposed regulations had provided that the statement "General Classification—available to the public" must appear following the heading "Direction for Use." These commenters suggested that this label statement be permitted on the front panel of the pesticide product, as well. EPA feels that emphasizing the general classification of the product is likely to mislead the public. Therefore, the suggestion of these commenters has been rejected and the statement of general classification has been modified to delete the phrase "available to the public." In addition, explicit language has been added to § 162.10(j)(1) to indicate that any reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use is considered a false or misleading statement within the meaning of section 2(q)(1)(A) of the Act.

Section 162.11 *Criteria for Determinations of Unreasonable Adverse Effects.* Several commenters objected generally to § 162.11 on the grounds that utilizing specific criteria for determining "unreasonable adverse effects", as that term is applied to registration, cancellation and classification decisions, is arbitrary and premature. Little if any direct justification for this charge was included with these comments, nor were specific suggestions made for improving the criteria. Other commenters suggested that the Agency include a criterion for determining the acute toxicity hazard posed by a product as diluted for use. Finally, some commenters criticized the proposed regulations for failing clearly to set forth the procedures for applying the criteria in reaching a final decision.

In order to respond to these comments, both general and specific, the Agency has significantly expanded its preamble discussion of the scientific, policy and legal justification for the individual criteria selected. In some cases, the criteria were modified and the rationale for the modification is clearly set forth. The Agency agrees with the comment that criteria for use dilution are appropriate in assessing some forms of exposure to acutely toxic pesticides. The criteria selected and the reasons for adopting use—dilution criteria are included below. Finally, the procedures for applying the criteria, the method of rebuttal, and the standard to be applied at the various stages of review are all set forth in the regulations. An extensive discussion of these procedures and the legal justification for them is included below.

The title of this Section, as proposed, was "Unreasonable Adverse Effects." A commenter noted that this proposed title suggested that all registered pesticides would give rise to "unreasonable adverse effects." Since the Section's primary function is to specify the conditions which determine whether a pesticide is to be registered and how its uses are to be classified, and since these determinations ultimately depend upon an evaluation of the pesticide's potential to cause unreasonable adverse effects, the title of the Section is changed to: "Criteria for Determinations of Unreasonable Adverse Effects."

A. *Statutory Standards.* The basic environmental standard for major regulatory determinations under FIFRA, as amended, is "unreasonable adverse effects on the environment." The term is defined by section 2(bb) of the Act to mean "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide." The term "environment" as defined by section 2(j) "includes water, air, land, and all plants and man and other animals living therein, and the interrelationships which exist among these." FIFRA applies the statutory standard in five separate contexts: (1) In determining whether to approve or deny an application for registration

(FIFRA sec. 3(c) (5) and (6)); (2) in determining whether to issue notice of intent to cancel registration or to hold a hearing (FIFRA sec. 6(b)); (3) in determining whether finally to cancel registration (FIFRA sec. 6(d)); (4) in determining whether to suspend a registration pending the completion of a cancellation proceeding (FIFRA sec. 6(c)); and (5) in determining whether a pesticide should be classified for general or restricted use (FIFRA sec. 3(d)(2)). If the statutory tests demanded precisely the same determination in each of these different contexts, it would be impossible for EPA to perform these distinct regulatory functions. Moreover, it is inconceivable that the determination needed to trigger the formal administrative review would be the same as that required to make a final determination after such review has been completed. Congress obviously intended that the determinations required in applying the statutory test in these different contexts would vary according to the purpose of each different regulatory function. Therefore, EPA must apply different factors and criteria in determining "unreasonable adverse effects on the environment" depending on the specific regulatory determination involved. Those factors and criteria which EPA has determined are relevant to the particular determinations of "unreasonable adverse effects on the environment" are contained in § 162.11.

B. *Administrative and Judicial Interpretations of the Statutory Standard.* In developing the criteria for registration, classification, and cancellation, the Agency has been guided by the administrative and judicial interpretations of the basic statutory standard. These interpretations are set forth in orders issued by the Administrator in court decisions in review of the Administrator's orders. The Administrator has determined that in applying the standard of "unreasonable adverse effects" for purposes of denial or cancellation of registration, a notice of denial or cancellation or notice of intent to hold a hearing to determine whether the registration should be denied or cancelled, as appropriate, shall be issued when he has determined that a substantial question of safety exists as to the use or continued use of the pesticide and that applicable court decisions require that such notice be issued under these circumstances.

The Administrator has further determined that the regulatory actions specified in this § 162.11 are in accordance with his prior orders and court decisions affirming those orders. The basis for these determinations is more fully set forth in the following discussion.

1. *Substantial Question of Safety: Initiation of the Formal Hearing Process.* In *Environmental Defense Fund, Inc.* v. *Ruckelshaus*, 439 F. 2d 584 (D.C. Cir. 1971), hereinafter referred to as *EDF* v. *Ruckelshaus*, EDF challenged, among other things, the Secretary of Agriculture's refusal to issue a cancellation notice regarding all registered uses of DDT, which would have set the formal administrative hearing process in motion. Acting under FIFRA prior to the 1972 amendments, the Secretary refused to issue the notice pending further study of the benefits of the uses of DDT and the adequacy of substitutes, although he had found that use of DDT poses a substantial risk to man and the environment.[9] The court held that FIFRA required issuance of a cancellation notice when there was a substantial question of safety regarding continued use of the pesticide and that the weighing of benefits against such risk should occur in a public forum:

> The legislative history supports the conclusion that Congress intended any substantial question of safety to trigger the issuance of cancellation notices, shifting to the manufacturer the burden of proving the safety of his product.
>
> For when Congress creates a procedure that gives the public a role in deciding important questions of public policy, that procedure may not lightly be sidestepped by administrators. The cancellation decision does not turn on a scientific assessment of hazard alone. The statute leaves room to balance the benefits of a pesticide against its risks. The process is a delicate one, in which greater weight should be accorded the value of a pesticide for the control of disease, and less weight should be accorded its value for the protection of a commercial crop. The statutory scheme contemplates that these questions will be explored in the full light of a public hearing and not resolved behind the closed doors of the Secretary. There may well be countervailing factors that would justify an administrative decision, after committee consideration and a public hearing, to continue a registration despite a substantial degree of risk, but those factors cannot justify a refusal to issue the notices that trigger the administrative process. 439 F.2d at 593–4.

In rejecting the notion that cost/benefit analysis was required prior to the initiation of public hearings the court observed that:

> Public hearings bring the public into the decisionmaking process, and create a record that facilitates judicial review. If hearings are held only after the Secretary is convinced beyond a doubt that cancellation is necessary, then they will be held too seldom and too late in the process to serve either of these functions effectively. Id. at 595.

The administrative hearing also serves the important function of affording the registrant an opportunity to challenge the Agency's determination that the pesticide poses a substantial question of safety and to establish that the benefits of use outweigh the risks.

Since the decision in *EDF* v. *Ruckelshaus*, every court which has addressed the question has embraced the "substantial question of safety" rule.[10]

In *Dow Chemical Company* v. *Ruckelshaus*, 477 F.2d 1317 (1973) the Court of Appeals for the Eighth Circuit recognized that cancellation of pesticide registrations under FIFRA "is a situation of extreme complexity, interweaving economic pressures with the most basic considerations of human safety." 477 F.2d at 1326. Dow Chemical Company challenged the Administrator's notice of intent to cancel 2,4,5-T for failure to make ultimate findings of the unacceptability of the pesticide in determining to issue that notice. The court held that the cancellation notice was not reviewable since it "merely sets in motion the administrative process that terminates in a reviewable final order." 477 F.2d at 1323. In so ruling the court adopted the "substantial question of safety" test for issuance of notices of cancellation and rejected Dow's claim that such a notice may not be issued until the Administrator has made the ultimate finding required by FIFRA:

> Since the registrant has a continuing burden of proof to establish that its product is entitled to registration, Southern Nat'l Mfg. Co. v. EPA, 470 F.2d 194 (8th Cir. 1972), if the Administrator has a substantial doubt as to safety, it is his duty . . . to issue the cancellation order. And the cancellation order will remain in effect until the registrant satisfies the Agency that registration is warranted. 477 F.2d at 1324–5 (footnote omitted).

In *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 465 F.2d 528 (D.C. Cir. 1972), a case arising under FIFRA prior to the 1972 amendments, EDF challenged the Administrator's refusal to suspend the registrations of Aldrin/Dieldrin on the basis that in balancing risks and benefits he failed to consider the adequacy of substitute pesticides. The suspension procedure at issue provided for suspension effective immediately without a prior public hearing—a procedure equivalent to the emergency suspension of FIFRA § 6(c)(3). Stating that [w]e are not clear that the FIFRA requires separate analysis of benefits at the suspension stage . . . ." the court nevertheless agreed with EDF that having undertaken risk/benefit analysis, the Administrator was required fully to consider pest control alternatives. Having acknowledged that the Administrator may weigh risks and benefits in a summary suspension determination, the court distinguished that determination from the initiation of cancellation proceedings where the only standard "for the issuance of cancellation notices" is "substantial question of safety." 465 F.2d at 533.

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[9] Prior to the 1972 amendments, FIFRA provided for a determination that a notice of cancellation should be issued if, among other things, continued use of the pesticide would be "injurious to living man" or the environment.

[10] *Environmental Defense Fund* v. *Environmental Protection Agency*, 510 F.2d 1292 (D.C. Cir. 1975), *Dow Chemical Co.* v. *Ruckelshaus*, 477 F.2d 1317, 1319 (8th Cir. 1973); *Environmental Defense Fund* v. *Environmental Protection Agency*, 465 F.2d 528, 533 (D.C. Cir. 1972); *Stearns Electric Paste Co.* v. *Environmental Protection Agency*, 426 F.2d 293, 307 (7th Cir. 1972); *Wellford* v. *Ruckelshaus*, 439 F.2d 598, 601 (D.C. Cir. 1971).

Accordingly, in cases arising under FIFRA prior to the 1972 amendments, the courts have uniformly held that where a substantial question of safety as to use of a pesticide is found to exist, provision must be made for an opportunity for balancing the risks against the benefits of use of the pesticide in a public hearing.

The legislative history states that the effect of these decisions under the pre-1972 statute is not changed by the 1972 amendments, but rather is incorporated in the revised statute. The Senate Committee on Agriculture and Forestry stated in its report on the 1972 amendments to FIFRA that the amendments "carry forward" existing law: notice of intent to cancel registration must be issued "where a substantial question of safety exists." Senate Committee on Agriculture and Forestry, S. Rep. No. 92–838, 92d Cong. 2d Sess. 12–13 (1972); *See also* Committee of Conference, Federal Environmental Pesticide Control Act, S. Rep. No. 92–1540, 92d Cong. 2d Sess. 32 (1972) ("[the amended FIFRA] preserves cancellation criteria in existing law").

This view has also recognized in the adoption of section 16(a) of the amended FIFRA which provides that the decision *to* register or *not to* cancel registration shall be reviewable in district court where a trial *de novo* would be conducted solely to determine whether a substantial question of safety existed. The Senate Agriculture Committee Report on section 16(a) stated that:

> Where, however, the Administrator has determined no substantial question of safety exists which warrants formal review, and thus has refused to hold a hearing, review should be by a district court since there is no record for the court of appeals. *Id.* at 13.

Thus, under the 1972 amendments, Congress intended that "unreasonable adverse effects" as applied to the issuance of denial and cancellation notices would be determined by the presence of a "substantial question of safety." As applied to a decision finally to deny or cancel registration, the determination of "unreasonable adverse effects" would include, in addition, a balancing of risks and benefits.

In its April 4, 1975 decision affirming the Administrator's order suspending registrations of Aldrin and Dieldrin, the United States Court of Appeals for the District of Columbia Circuit reiterated in *Environmental Defense Fund* v. *Environmental Protection Agency*, 510 F. 2d 1292 (1975), that the "substantial question of safety" test remains the basis for issuing a notice of intent to cancel or deny registration under the provisions of the 1972 amendments to FIFRA. 510 F.2d at 1296, n 4. Citing the 1972 amendments to FIFRA, the Court emphasized its earlier holding in *EDF* v. *Ruchelshaus, supra* (1972) that "* * * FIFRA requires the Secretary to issue cancellation notices and thereby initiate the administrative process whenever there is a substantial question about the safety of a registered pesticide." *Id.*

Where a substantial question of safety is found to exist, the regulations provide, in accordance with Court decisions and legislative intent, that a notice of intent to deny registration, a notice of intent to cancel registration, or a notice of intent to hold a hearing to determine whether the registration should be cancelled or denied, must be issued. Following issuance of the notice and convening of a hearing, the regulations provide, in accordance with court decisions and legislative intent, an opportunity for the risks and benefits from use of the pesticide to be fully considered and weighed in a public forum.[11]

FIFRA makes a procedural distinction between denials of registration and cancellation of registration. In the case of a new application for registration, the Administrator may grant or deny registration. The effect of denial is to prevent the pesticide from being introduced into commerce until administrative procedures—such as section 3(c)(6) hearings—have been exhausted. In the case of an existing registration, however, the Administrator may either continue the registration or cancel the registration. Unless the registrant fails to request a hearing within 30 days of the initial cancellation order, cancelled registrations remain in full force and effect until after a decision has been reached on the record by the Administrative Law Judge, and by the Administrator if the case is appealed to him.

Because of these inherent differences in the statutory procedures for denial and for cancellation, which allow continued use of cancelled pesticides pending a final decision following an administrative hearing, FIFRA also provides for accelerated procedures with respect to cancelled pesticides. In accordance with FIFRA section 6(c), where the Administrator finds that "action is necessary to prevent an imminent hazard during the time required for cancellation or change in classification proceedings * * *" he may by order suspend the registration after providing an opportunity for an expedited hearing on the question of "whether an imminent hazard exists."

In addition, where he finds that such an imminent hazard exists, the Administrator may issue an emergency order suspending registration effective immediately pending completion of the expedited suspension hearing. The term "imminent hazard" is defined by FIFRA section 2(1) to mean "a situation which exists when the continued use of a pesticide during the time required for cancellation proceeding(s) would be likely to result in unreasonable adverse effects on the environment or will involve unreasonable hazard to the survival of a species declared endangered by the Secretary of Interior under Pub. L. 91–135."

Thus, the statutory test of unreasonable adverse effects which applies to denials of registration and to cancellations also applies to suspensions, and, before a suspension order may be issued, the cancellation process must have been initiated. Section 6(c)(1). Therefore, the regulations do not set forth procedures governing suspension but it is appropriate briefly to set forth recent case law which will guide the Agency's determination as to the presence of an "imminent hazard."

The courts have repeatedly "cautioned that the term 'imminent hazard' is not limited to a concept of crisis: 'It is enough if there is *substantial likelihood* that serious harm will be experienced during the year or two required in any realistic projection of the administrative (cancellation) process.'." *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 510 F.2d at 1297 (D.C. Cir. 1975). (Emphasis in original) quoting from *Environmental Defense Fund, Inc.* v. *Environmental Protection Agency*, 465 F.2d at 540 (D.C. Cir. 1972). Of course, as in the cancellation proceeding, the Administrator does not have the burden of proving that a pesticide is unsafe since the statute and case law place "[t]he burden of establishing the safety of a product requisite for compliance with the labelling requirements * * * at all times on the applicant and registrant." *EDF* v. *EPA*, 510 F.2d at 1297 (D.C. Cir. 1975); *EDF* v. *EPA*, 465 F.2d at 540 (D.C. Cir. 1972).

The courts have consistently held that "the function of the suspension decision is to make a preliminary assessment of evidence and probabilities, not an ultimate resolution of difficult issues. We cannot accept the proposition * * * that the Administrator's findings [are] insufficient because controverted by respectable scientific authority. It [is] enough that the administrative record contain respectable scientific authority supporting the Administrator." *EDF* v. *EPA*, 510 F.2d at 1298 (D.C. Cir. 1975); *EDF* v. *EPA*, 465 F.2d at 537 (D.C. Cir 1972).

The courts have distinguished between cancellation and suspension by requiring that cancellation notices issue whenever there is a substantial question of safety and defer thorough consideration of benefits to the public forum, whereas in the case of suspension, "the statute empowers the Administrator to take account of benefits or their absence as affecting imminency of hazard." *EDF* v. *EPA*, 465 F. 2d at 538 (D.C. Cir. 1972). Accordingly, within the constraints imposed by FIFRA and by case law as explained briefly below, the Agency intends to continue evaluating the need for suspension by taking into account, upon issuance of a notice of intent to cancel in accordance with these regulations, risks and benefits of use, the expected length of any cancellation proceedings; any relevant manufacture, distributing, or use cycle; and any other pertinent factors.

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[11] Prior to the 1972 amendments, FIFRA did not explicitly require that the risks (costs) and benefits of use be balanced in finally determining the registration or cancellation of pesticides. However, as the Administrator noted in the DDT order, the balancing test had long been established. "Both judicial and administrative precedent recognize that Congress intended the application of a balancing test, that would measure the risks of using a particular chemical against its benefits." Order, Consolidated DDT Hearings, Opinion and Order of the Administrator, 37 FR 13369 (July 7, 1972).

2. *Test data for evaluation of risk.* In determining the factors and criteria for initiating a cancellation or denial proceeding because of "unreasonable adverse effects on the environment" and for issuing final orders in such proceedings, the Administrator has been guided by the general principles and policies developed in previous cancellation and suspension proceedings which have been affirmed by United States Courts of Appeal. The first major EPA action brought against a pesticide because of environmental and human health risks was the cancellation of DDT which was finally decided by the Administrator on June 14, 1972[12] and subsequently affirmed by the United States Court of Appeals for the District of Columbia Circuit on December 13, 1973.[13]

In finding that DDT should be cancelled, the Administrator applied several general principles and policies which have also been applied in other proceedings and are adopted in these regulations. First, in assessing the risks of the use of a pesticide, both short-term and long-term effects on man and other organisms must be determined and considered.

Second, the actual observations of long-term, chronic effects, particularly on man through epidemiological studies, are of limited value in determining the registrability of a pesticide, since once the effects are actually observed in man or the environment, the harm has already occurred and may be irreversible. Therefore, extrapolation from laboratory studies on animals must be utilized to assess risks to man or the environment. As the Administrator stated in the Order:

> It is particularly difficult to anticipate the long-range effects of exposure to a low dose of a chemical. It may take many years before adverse effects would take place. Diseases like cancer have an extended latency. Mutagenic effects will be apparent only in future generations. Lastly, it may be impossible to relate observed pathology in man to particular chemical because of the inability to isolate control groups which are not exposed in the same degree as the rest of the population.[14]

On December 13, 1973, the United States Court of Appeals for the District of Columbia affirmed the Administrator's Opinion and Order holding that his decision was supported by "substantial evidence."[15] Moreover, in reviewing the Administrator's decision the Court emphasized the expertise of the Agency in evaluating the environmental and human health risks of the use of chemicals and appropriately deferred to the expert conclusions reached by EPA even in the face of conflicting scientific opinion.

> * * * we as a court are confronted with a problem in administrative law, not in chemistry, biology, medicine, or ecology. It is the administrative agency which has been called upon to hear and evaluate testimony in all scientific fields relevant to its ultimate question of permission or prohibition of the sale and use of DDT. The EPA Administrator had an opportunity to make a careful study of the record of seven months of public hearings and the summaries of evidence prepared for him, heard oral argument, and now has arrived at a decision to ban most uses of DDT. It is his decision which we must review; we are not to make the same decision ourselves. *Id.* at 1252.

Specifically, the Court held that the use of laboratory data, general data, and recognition of the inherent chemical characteristics of pesticides were sufficient as a mater of law to determine that a pesticide should not be registered.

> Reliance on general data, consideration of laboratory experiments on animals, etc., provide a sufficient basis to support the Administrator's findings, even with regard to each special use of DDT. *Id.* at 1254.

Furthermore, the Court held that the Administrator was not required to determine and balance the risks and benefits of each specific use of a pesticide to determine that "the use [of a pesticide] in general is hazardous" and therefore cannot be registered or continue to be registered.

The general principles and policies set forth in the DDT cancellation opinion and order recently were applied and expanded in the decision of the Administrator to suspend virtually all uses of the pesticides Aldrin and Dieldrin.[16] As in the case of the decision to cancel DDT, the decision to suspend Aldrin and Dieldrin was based on several years of administrative inquiry into the risks of Aldrin and Dieldrin and many months of cancellation hearings, evidence of which was incorporated into the suspension hearing. The Administrator's opinion, which considered and was preceded by an extensive recommended decision by the Chief Administrative Law Judge[17] who presided during the cancellation hearings and the suspension hearings, focused on the single issue of the carcinogenic risk of Aldrin and Dieldrin. Before deciding whether there was sufficient evidence to find a carcinogenic risk from Aldrin and Dieldrin, the Administrator, as did the Administrative Law Judge in his recommended decision, set forth the general theories for evaluating the carcinogenicity evidence on Aldrin and Dieldrin. First, the Administrator affirmed the scientific validity and administrative necessity of using experimental animal data in evaluating the risks pesticides pose to man and the environment.[18] Second, as in the DDT Order, he rejected the notion that in the face of positive laboratory data of carcinogenicity, regulatory decisions which will directly affect the public health must be deferred pending completion of epidemiological studies which require many years and in any event provide data for making public health decisions only after the public health may have been irreversibly jeopardized. Third, the Administrator questioned the results of epidemiological studies where the chemical is environmentally ubiquitous and all populations have received chronic exposure.[19] Fourth, the Administrator rejected the distinction between "benign" and "malignant" tumors and "tumorogenic" and "carcinogenic substances" for purposes of hazard evaluation because of "the increasing evidence that many tumors can develop into cancers." He determined that "for purposes of carcinogenicity testing, they should be considered synonymous."[20] Finally, the Administrator agreed with the finding of the Administrative Law Judge that no safe level of exposure could be set for the pesticides Aldrin and Dieldrin which had been demonstrated to be carcinogenic in animals, even at very low levels. Accordingly, the Administrator concluded that "a substance that will induce cancer in experimental animals at any dose level, no matter how high or low, should be treated with great caution."[21]

On April 4, 1975, the Court of Appeals for the District of Columbia in *Environmental Defense Fund* v. *Environmental Protection Agency*, 510 F. 2d 1292, affirmed the Administrator's Order and Opinion. The Court upheld the Administrator's findings and policies set forth above as being within the expertise of the Agency. Specifically the Court stated:

> The Administrator's failure to determine a threshold level of exposure to aldrin/dieldrin does not render his determination improper, for he had concluded that the concept of a threshold exposure level has no practical significance where carcinogens are concerned. This is due in part to the irreversibility and long latency period of carcinogens. "[W]here the matter involved is as sensitive and fright-laden as cancer," and the statute places the burden on the registrant to establish the safety of his product, we shall not, assuming a substantial showing of danger, require the Administrator to make impossible proofs. In

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[12] Consolidated DDT Hearings, Opinion and Order of the Administrator, 37 FR 13369 (July 7, 1972).

[13] *Environmental Defense Fund* v. *Environmental Protection Agency*, 489 F. 2d 1247 (D.C. Cir. 1973).

[14] Opinion and Order, *supra*, footnote 19 at 13371.

[15] *EDF* v. *EPA*, 489 F.2d 1247.

[16] Shell Chemical Company, et al., Opinion and Order of the Administrator, 39 FR 37265 (Oct. 18, 1974).

[17] While the Order of the Administrator did not explicitly adopt the findings and reasoning of the Administrative Law Judge, it "is clearly implicit in and indeed suffuses his [the Administrator's] entire opinion, that he accepts the Administrative Law Judge's findings and reasoning except where a difference in commentary is made explicit." *EDF* v. *EPA*, 510 F. 2d at 1304 (D.C. Cir. 1975).

[18] *Id.* at 37270.

[19] These principles were recently reaffirmed by the Administrator in his decision to deny the State of Louisiana's request for emergency use of DDT on cotton. See, *Statement of Reasons for Denial* and *Supplemental Statement*, 40 FR 15934 (April 8, 1975).

[20] *Id.* at 37267

[21] Opinion, *supra*, at 37268.

> reviewing administrative actions, courts "cannot fairly demand the perfect at the expense of the achievable." The Administrator's conclusion is within the scientific expertise of the agency, and is not infected by error of law. *Compare Environmental Defense Fund, Inc.*, v. *Ruckelshaus, supra*, 142 U.S. App. D.C. at 86, 438 F. 2d at 596.
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> The validity of extrapolation to humans from data derived from tests on animals is also a matter within the agency's expertise. There was testimony before the Administrator to support such extrapolation, and this court has acknowledged the significance of test animal data when cancer is involved. Use of animal data is particularly appropriate where, as here, accurate epidemiological studies cannot be conducted because the virtually universal contamination of humans by residues of aldrin/dieldrin make it impossible to establish an uncontaminated human control group. The long latency period of carcinogens further hinders epidemiological research, and the ethical problems of conducting cancer experiments on human beings are too obvious to require discussion. Although extrapolation of data from mice to men may be quantitatively imprecise, it is sufficient to establish a "substantial likelihood" that harm will result. [Citations omitted], *Id.* at 1298–1299.[22]

Finally, the Court affirmed the Administrator's balancing of the risks and benefits of the use of Aldrin and Dieldrin in his decision to suspend, noting that if the EPA suspends, as in the case of Aldrin and Dieldrin, the burden is on the proponent of registration "to establish that continued registration poses no safety threat" or "that the benefits outweigh the risks." *Id.* at 1302.

In accordance with the principles of hazard evaluation in the exhaustive DDT and Aldrin/Dieldrin administrative and court proceedings, the use of animal test data is the foundation for hazard evaluation criteria for new and old pesticide products. Such data are used to evaluate both the short term and the long term effects from the use of a pesticide; therefore, in § 162.11, both acute and chronic effects criteria are set forth. The hazard of acute effects, as is explained below, generally can be quantified on a comparative scale. The hazard of chronic effects, however, is generally not subject to precise quantification and must be evaluated as part of a qualitative assessment of risk. In the following sections, the specific criteria for assessing both acute and chronic effects and the rationale for the selection of specific criterion are set forth. As explained below, these criteria serve as initial hazard indicators which set more formal procedures in motion to determine classification, registration and cancellation. The criteria do not impose additional data requirements. Data requirements are set forth in § 162.8 and the corresponding sections of the Registration Guidelines.

C. *Acute Toxicity Criteria.* Several commenters questioned the propriety of utilizing numerical toxicity criteria as hazard indicators for the dual purpose of determining whether, as an initial matter, a pesticide should be classified for general or restricted use and whether a pesticide is subject to a rebuttable presumption against registration or continued registration. For the reasons set forth below, the Administrator has determined that such toxicity criteria are valid indicators of presumptive hazard and serve the important regulatory function of screening those pesticides which require additional scrutiny to determine whether they should be registered or, if registered, whether they should be classified for general or restricted use. As discussed below, the particular numerical criteria employed vary according to the anticipated rate of exposure, type of use, and anticipated hazard.

1. *Existing Numerical Criteria.* Numerical toxicity criteria have, of course, been used in this country and abroad as indicators of hazard for many years. In 1949 Hodge devised a numerical scale in which chemicals were classified into groups categorized by simple descriptive phrases—"extremely toxic," "highly toxic," "moderately toxic," etc.—using the oral LD_{50} as the numerical criterion for categorization.[23] This scale was subsequently modified by Gosselin to apply to formulations rather than technical chemicals with the object of preventing poisoning, since the formulated product had wider distribution and exposure than the technical material. Gosselin's scale was further modified and expanded by inclusion of numerical criteria (LD_{50} or LC_{50}) representing dermal and inhalation toxicity and formed the basis of regulatory interpretations under the 1947 FIFRA, to determine the warning (signal) words and precautionary statements required to appear on a product label.[24]

a. *Use of existing toxicity categories for precautionary labeling.* This same method is used for determining the appropriate signal word and precautionary statement for labeling purposes under these regulations, although some modifications have been made to the inhalation and skin and eye irritation criteria. Thus, numerical toxicity categories are established for formulated products based on dermal, inhalation, and oral LD_{50} or LC_{50} values; and qualitative descriptors are used to evaluate skin and eye effects. For instance, if a particular formulation has a dermal LD_{50} of 200 mg/kg or less, it falls into the highest toxicity category and must bear on its label the signal word, "Danger," and the precautionary statement, "Fatal (Poisonous) if absorbed through skin. Do not breathe dust [vapor or spray mist]. Do not get in eyes, on skin or on clothing." In addition, the label must bear a statement of practical treatment on the front panel. See § 162.10(i): Few commenters questioned the continuation of this system, as modified, for labeling determinations.

b. *Existing toxicity categories for classification of pesticides.* In enacting the comprehensive 1972 amendments to FIFRA, Congress recognized that these long-standing label requirements had not been adequate, standing alone, to protect the pesticide user or other persons from the adverse effects of exposure to acutely toxic pesticides. Accordingly, section 3(d) of the amended Act directs the Administrator to classify pesticides either for general use or for restricted use. Pesticides classified for restricted use will be restricted to use by certified applicators or subject to other regulatory restrictions.

Section 3(d)(1)(C)(i) of the Act specifically requires the Administrator to restrict a pesticide's use to certified applicators if the pesticide is classified for restricted use based on its acute dermal or inhalation toxicity. As discussed above, the established method for determining acute toxicity is based upon laboratory procedures that establish doses lethal to 50% of the test animals. This method was utilized prior to the 1972 amendments to protect the user through labeling. Accordingly, the Administrator concluded that it was reasonable to apply the same system, including equivalent numerical criteria, when determining as an initial matter that a pesticide was too hazardous to be classified for general use. Established as hazard indicators, the toxicity categories serve expressly that function in the classification scheme by acting as an initial screen for classification. An applicant, however, as discussed elsewhere in this preamble, is provided the opportunity to demonstrate to the Administrator that a pesticide which meets the toxicity criteria for restricted use should nevertheless be classified for general use because its labeling, formulation, packaging, or method of use could reasonably be expected to minimize the likelihood of hazard.

The classification scheme is further refined in that more stringent criteria are set for pesticides registered for domestic use (in and around homes and certain areas of educational and health related institutions) than for non-domestic use. Specifically, if a pesticide formulation intended for domestic use falls into toxicity category I or II, it is considered a candidate for restricted use; if the formulation is intended for non-domestic use, it is considered a candidate for restricted use if its dermal or inhalation toxicity or skin or eye effects places it in toxicity category I. These toxicity categories are used explicity in § 162.11(c)(2) which specifies criteria for classifying pesticides for reregistration. The same criteria are used in § 162.11(c)(1) which specifies criteria for classifying newly registered pesticides. Further protection to the user is provided by classification criteria in these sections based on chronic or delayed toxic effects, discussed *infra*, and by §§ 162.11(c) (3) and (4) which require consideration of adequacy of labeling, use history, accident data, and other appropriate factors.

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[22] The Court also affirmed the Administrator's use of mice data in assessing the carcinogenic hazard of Aldrin and Dieldrin despite strenuous objection by the petitioners that mice are not valid indicators of human carcinogens.

[23] Hodge, H. C. and J. H. Sterner, *Tabulation of Toxicity Classes*, 10 AMER. INDUSTR. HYG. ASSOC. Quart., 93–95 (1949).

[24] For a discussion of history and development of the LD_{50} test, see *Principles and Procedures for Evaluating the Toxicity of Household Products*, NATIONAL ACADEMY OF SCIENCES—NATIONAL RESEARCH COUNCIL, Publication 1138 (1964), and Loomis, Ted A., *Essentials of Toxicology*, LEA & FEBIGER, Philadelphia (1968). The value obtained for the LD_{50} from an experiment with a finite number of test animals is on a statistical basis, an estimate of the actual dose required to kill 50% of an exposed population.

2. *Additional Numerical Criteria for Protection Against Hazards not covered by Existing Categorization.* The LD_{50} and LC_{50} criteria used to define the toxicity categories are the experimental values determined for the formulated product. The degree of acute toxicity of the formulated product is determined in order to protect users from accidental exposure during handling and storage. However, human exposure to pesticides also occurs during and after application of the pesticide. These activities involve, in many cases, the application of a substance that has been diluted from a concentrated formulation. Therefore, to protect applicators and other exposed persons, including children, from hazardous exposure to pesticides during and after use, it is necessary to apply numerical criteria based on the toxicity of the pesticide as diluted for use. Depending on the degree of dilution, such criteria may be more or less stringent than those imposed on the formulated product. In addition, three criteria have been included for pesticides intended for outdoor application to protect against hazards to wildlife. The criteria are based on the amount of active ingredient which will remain after the application of the use diluted product.

Three steps are involved in the setting of these numerical criteria: (i) determination of the principal types of exposure which pose hazards; (ii) estimation of exposure levels encountered under conditions of use of the product or of similar products; and (iii) application of a safety factor to provide a margin of safety for individuals exposed to these levels.

The purpose of the following discussion is to explore each one of these steps in detail in order fully to explain the Agency's choice as to a particular number. The discussion immediately below sets forth general principles of exposure to acutely toxic pesticides and describes the anticipated hazard of such exposure as developed from field surveys and numerous publications. The next section discusses the selection of appropriate safety factors to address the anticipated hazard.

The final section explains the Agency's choice of criteria, including an explanation of why, in a particular case, the general principles of exposure, hazard, and selection of safety facts were or were not fully utilized.

a. *Types of exposure posing demonstrable hazard under conditions of general use.* Published surveys[illegible] suggest that pesticide poisonings constitute a significant amount of all chemical poisonings in the United States and that most incidents of human poisonings by pesticides fall into one of two categories: poisoning of children, usually in the home, and poisoning of applicators. Hayes has reported that, depending on the sample year, pesticides have accounted for 6 to 13 percent of all poisoning from solids or liquids—with an estimated fatality rate of 0.65 per 1,000,000 or approximately 150–200 people per year and a rate of nonfatal to fatal poisonings of 100 to 1 or approximately 15,000–20,000 persons per year. Furthermore, of those poisonings approximately one-half involve children under ten years with the most significant portion involving children under 5 years. Occupational poisonings account for an estimated 15 percent of poisonings with pesticide applicators experiencing the highest rate and manufacturing workers experiencing the least number.[illegible] These estimates have not been corroborated by the Agency; however, we have determined that they indicate the scope of the hazard arising from pesticide use.

In the case of wildlife, most documented cases of substantial immediate damage refer to poisoning of mammals and birds feeding on contaminated food or on treated baits, or to kills of fish and other aquatic organisms resulting from contamination of shallow waters.[illegible] Toxicity to nontarget insects and other beneficial invertebrates is often of significance[illegible] but is difficult to prevent by means of classification.

b. *Estimating exposure levels for critical types of exposure.* The most important determination for assessing the hazard posed by an acutely toxic pesticide is the estimated exposure level likely to result from normal use. If that level is sufficient to produce an adverse effect, exposure must be limited through improved application techniques and the use of protective clothing, and other proper safety procedures. Even the most acutely toxic pesticide can probably be used safely if the applicator follows proper use and safety procedures to avoid a hazardous exposure. Conversely, a dose of a much less acutely toxic pesticide can result in severe injury through avoidable accident or improper negligent application techniques and procedures. In amending the Act, Congress found that substantial numbers of users of pesticides did not follow label directions and overused and misused pesticides. Congress, through Section 4 of the amended Act, addressed these problems by requiring that only applicators who have demonstrated competence be allowed to use acutely toxic pesticides. Applicators can be certified under the provisions of Section 4 if they have demonstrated their competence to use acutely toxic pesticides safely by avoiding dangerous exposure to themselves and other nontarget organisms. Accordingly, in determining the classification criteria for acute toxicity, it is essential that EPA estimate the amount of exposure likely to be experienced by both the applicator and by other persons, including bystanders and children, as a consequence of improper application. If the exposure levels would result in toxic doses or doses that have unreasonably small margins of safety, the pesticide should be classified for restricted use.

The exposure an applicator will receive in handling or applying a pesticide or the exposure any individual will receive as a result of the pesticide's application can then be related to the LC_{50} and LD_{50} doses obtained in laboratory experiments to determine the approximate danger associated with that level of exposure. Exposure during application is largely to the product as diluted for use. Accordingly, the use-dilution LD_{50} has been added as a classification screening measure. The numerical criterion is computed as explained below.

(1) *Dermal exposure to applicators: outdoor spray application.* Extensive measurements are available of the amount of exposure to applicators and others during routine pesticide applications carried out according to customary practices. Summarizing their own work

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[illegible] *Report of the Secretary's Commission of Pesticides and their Relationship to Environmental Health*, U.S. DEPT. HEALTH, EDUCATION, AND WELFARE, 304–319 (December 1969); Davies, J. E., *et al. Epidemiology and Chemical Diagnosis of Organophosphate Poisoning*, In "Pesticide Symposium" (W. B. Deichmann and J. L. Radowski, eds). Ind. Med. Publishing Co., Miami (1969), Lande, S. S., *An Epidemiological Study of Pesticide Exposure in Allegheny County, Pennsylvania*, 29 ARCH. ENVIRON. HEALTH, 90–96 (1974), Hayes, W. J., *Pesticides and Human Toxicity*, 160 ANN. N.Y. ACAD. SCI., 40 (1969), Hayes, W. J., *Epidemiology and General Management of Poisoning by Pesticides*, 17 PEDIATRIC CLINICS OF NORTH AMERICA, 629 (1970); Lisella, F. S., *Epidemiology of Poisoning by Chemicals*, 34 JOURNAL OF ENVIR. HEALTH, 608 (1972), and Whittock, N. W., Keil, J. E., and Sandifer, S. H., *Pesticide Morbidity in South Carolina, Revisited*, 68 JOURNAL OF THE SOUTH CAROLINA MEDICAL ASSN., 109 (1972).

[illegible] Hayes, *Pesticides and Human Toxicity*, *supra* 40–45. Hayes reports that for California, one of few states with a mandatory accident reporting system, pesticide work injuries for 1960–63 ranged from 827–1,013. For the same period approximately 20 percent of the deaths caused by pesticides occurred from occupational exposure. For the period 1964–67, California had reported an annual average of 1,300 occupational poisonings. Hayes, *Epidemiology and General Management of Poisoning by Pesticides*, *supra* at 634.

[illegible] *Report of the Secretary's Commission on Pesticides and their Relationship to Environmental Health*, U.S. DEPT. OF HEALTH, EDUCATION, AND WELFARE (Dec. 1969) pp. 177–223.

[illegible] Rudd, R. L., *Pesticides and the Living Landscape*. UNIV. OF CALIFORNIA PRESS (1964).

and that of others, Wolfe *et al.*[29] tabulated over 80 exposure studies involving more than 5,000 measurements of exposure to 23 pesticide chemicals in a variety of formulations and under a variety of methods of application. In most studies the dermal and respiratory exposures to the active ingredient were measured and the use dilution was stated. If all of the active ingredient as measured by Wolfe, *et al.* was assumed to be residues of the use-diluted product, then the ratio of the residue to the dilution rate would give an accurate measure of exposure to the use-diluted product. In fact, however, the measured active ingredient residue resulted from total exposure to the applicator from both exposure to the use-diluted product and the formulated product. Therefore, the ratio of active ingredient residue to dilution rate overestimates the amount of exposure attributable to the use-diluted product. Thus, a factor is included in the computation to calculate the amount of total exposure arising solely from application of the use-diluted product. The exposure studies cited above do not include data necessary for computing this factor. However, based on knowledge of the activities which were analyzed in the exposure studies, its value is estimated to be two.[30] The rates of measured exposure to the use-diluted product were then computed according to the following equation:

$$E = \frac{M}{D \times 10^{-2}} \div 2$$

where E = exposure rate to the use-diluted product (mg/hr)
D = rate of dilution (%)
M = measured value of exposure rate to active ingredient (mg/hr)

For outdoor spray applications, most of the dermal exposures measured by Wolfe *et al.* and computed by the above equation fell into the range 3–50 g/hr., calculated as the rate of deposition of the diluted product falling on the skin of an agricultural worker without special protective clothing; a number of individual measurements of dermal exposure were as high as 325 g/hr. Although the highest of these figures represent exceptionally bad practice, the measurements of Wolfe *et al.* indicate that dermal exposure levels of up to 125 g/hr to diluted product can be expected to occur during normal agricultural use, and exposures of up to 50 g/hr often occur even with experienced operators. Furthermore, Wolfe *et al.* has documented that users and applicators frequently fail to follow directions requiring protective clothing and respirators.[31] Based on an 8-hour working day by a 60 kg person, such practices would result in exposures of up to approximately 16 g/kg/day for the unskilled applicator and 6 g/kg/day for the skilled applicator respectively.[32]

(ii) *Dermal exposure to applicators: other formulations.* The above estimates of dermal exposures were derived primarily from measurements of exposure to spray formulations. The relatively few direct measurements of exposure from aerosol application indicates very little potential of hazard from exposure to the use-diluted product. However, since drift of droplets appears to be a major factor leading to higher exposures, products formulated as mists can be expected to give exposures similar to sprays.[33]

Other formulations, such as dusts and granules, are applied in undiluted form. Since the existing LD_{50} on the formulated product offers protection to the applicator from dermal exposure to the undiluted product, no additional criteria have been provided for formulations other than spray and mist.

(iii) *Indoor exposure.* Far fewer data are available on exposure levels to indoor users of pesticides. Although Wolfe *et al.* (1967) listed only two indoor studies, one of these involved a case in which indoor house spraying resulted in dermal and respiratory exposure to the active ingredient of 1,755 and 7.1 mg/hr respectively—some 2–3 times larger than the highest figures listed in the Wolfe studies[34] as resulting from outdoor use, suggesting that indoor uses may result in higher rates of exposure, both to applicators and to others exposed to the pesticides. However, the fact that pesticides are usually sprayed indoors only for short periods decreases the hazard. Accordingly, it is unlikely that typical indoor exposures would approach those experienced by outdoor users working for a full day. This finding is supported by accident data which do not indicate a substantial frequency of poisonings from indoor use other than accidental ingestions by children.[35] There is indirect evidence from residue monitoring that indoor uses are responsible for a substantial portion of the average person's exposure to pesticides,[36] but such low level exposure would involve subacute or chronic toxic effects rather than acute poisoning. Chronic toxicity hazards are addressed under the criteria of § 162.11 (c) (1) and (2). No criterion is included for dermal exposure to the use-diluted product in domestic situations.

(iv) *Respiratory exposures.* The measurements summarized by Wolfe *et al.* suggest that in most cases dermal exposures greatly exceed respiratory exposures, often by a factor of 50 or more.[37] The largest reported respiratory exposure was only 1.4 g/hr, to a spray formulation, and even in this case it is not clear that a substantial part of the material was in droplets small enough to enter the lungs. Accordingly, it seems likely that respiratory exposure would be of much less significance to applicators than dermal exposures. According to accident summaries, the principal hazards posed by respiratory exposures would be to small children and to asthmatics.[38]

(v) *Accidental exposure to children.* When pesticides are used in domestic situations, there is the possibility that the pesticides may be accessible to children or pets. As discussed above, poisoning statistics indicate that the possibility is frequently realized since approximately 60 percent of all poisonings involve young children. Labeling is of no value in preventing accidents if the child can gain access to the pesticide product. Studies of domestic accidents reveal several general characteristics of pesticide accidents affecting children. For children under 2 years old, exposure is generally by ingestion, particularly from bait pesticides, moth balls and rodenticides used in indoor treated areas. For children aged 2–5 years, oral exposure, particularly to stored pesticides, is very significant, as is eye and dermal exposure from all types of formulations but particularly from dust or granule formulations.[39] Exposure for children aged 2–5 occurs in all areas of pesticide use, both indoors and outdoors.[40]

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[29] Wolfe, H. R., W. Durham, and J. F. Armstrong, *Exposure of workers to pesticides.* 14 ARCH. ENVIRON. HEALTH, 622 (1967). Wolfe, H. R., J. F. Armstrong, D. C. Staiff, and S. W. Comer, *Exposure of spraymen to pesticides.* 25 ARCH. ENVIRON. HEALTH, 29 (1972).

[30] To illustrate:

If a measured active ingredient deposition of 10 mg was assumed to be the residue of a 5% use-diluted product, then the pesticide worker must have been exposed to $\frac{10\text{ mg}}{.05} = 200$ mg of use-diluted product.

However, if of the 10 mg active ingredient deposition, only 5 mg resulted from exposure to the use-diluted product, with the other 5 mg resulting from exposure to the undiluted formulation, then the worker was exposed to $\frac{5\text{ mg}}{.05} = 100$ mg of use-diluted product. The latter example reflects the introduction of a factor of two to account for the fact that the measured deposition occurs to workers, who in the course of their normal activities, are exposed to both diluted and undiluted products.

[31] Wolfe, H. R., J. F. Armstrong, D. C. Staiff, and S. W. Comer, *The Use of Protective Clothing and Equipment for Prevention of Exposure to Pesticides,* PROCEEDINGS OF THE NATIONAL CONFERENCE ON PROTECTIVE CLOTHING AND SAFETY EQUIPMENT FOR PESTICIDE WORKERS, 155 (1972).

[32] Wolfe, *et al.*, op. cit. (1967, 1972).

[33] Wolfe, *et al.*, op. cit. (1972).

[34] These figures refer to active ingredient exposure, not to the use dilution exposure derived in the preceding discussion.

[35] Hayes, *supra.*

[36] Radomski, J., Deichman, W. B. and Clizer, S. S., *Pesticide Concentrations in the Liver, Brain and Adipose Tissue of Terminal Hospital Patients,* 6 FD. COSMET. TOXICOL, 209–220 (1968).

[37] However, it must be noted that a pesticide is more rapidly and completely absorbed through the respiratory route than through the dermal route and therefore a small exposure may be toxicologically significant. Where indoor spraying is continued over a long period of time, exposure may be quite significant. For example, Wolfe *et al.* have reported that: "[I]n the case of DDT . . . indoor house spraying was about 4 times as hazardous as flagging for airplane dusting of fruit orchards, approximately 7 times as hazardous as outdoor house spraying, and over 30 times as hazardous as operating an air blast spray machine in a fruit orchard." *Wolfe et al., Exposure of Workers to Pesticides, supra* at 625.

[38] Lande, S. *An Epidemiological Study of Pesticide Exposures in Allegheny County, Pennsylvania,* 29 ARCH. ENVIRON. HEALTH. 90 (1974).

It is difficult to estimate the precise degree of exposure of small children to pesticides, but there is evidence from documented incidents of fatal and nonfatal poisonings that children aged 2 or less can easily ingest 5g of a pesticide.[41] Based on a typical weight of 10kg for such a child, exposures of up to 0.5 g/kg of the product as diluted for use would be expected, at least for these formulations. For older children up to 5 years (i.e., up to about 20 kg in weight) ingestion of up to 60g seems likely in the typical accident involving drinking from a bottle.[42] This exposure would be as large as 3 g/kg and might involve ingestion of the formulated (undiluted) product unless the product was sold in special packages designed for child protection.

There is less information on dermal exposures to children, although the frequency of significant poisonings by the dermal route indicates that dermal exposures may be as significant as oral exposures, particularly for children over 2 years of age.[43] Eye exposures are also significant for children in the age range 2–5. Both these factors have been taken into account in setting the classification criteria for skin and eye effects.[44]

(vi) *Exposure to sensitive wildlife.* Critical exposures to mammals and birds occur primarily through contamination of their food.[45] The precise routes of contamination and the species at greatest risk vary greatly with the type of formulation and the way in which the pesticide is applied. For example, baits and treated seeds may be eaten directly; sprays and dusts may contaminate vegetation or fruit used for forage; insects and fish may acquire sublethal residues and cause secondary poisoning. The most significant exposures can generally be predicted from experience with similar formulations of other pesticides; measurements of exposure levels can be obtained in test plots.

In the case of aquatic species, the most important exposure is usually through the water in which they live. Average exposure levels can be estimated by calculating the amount of pesticide that would be deposited per unit area of water surface under typical conditions of application (corresponding to the widespread pattern of use for the type of pesticide involved) and assuming that the material is uniformly mixed through the body of water. Most significant incidents of damage to aquatic animal populations (fish, shrimp, crabs, etc.) have taken place in shallow waters (marshes and streams less than 6 inches in depth). Further, many pesticides are formulated in such a way that they stratify in a thin layer at the surface or bottom of still waters. Accordingly, an average depth of 6 inches is selected as representative of the water bodies in which aquatic organisms are at risk. The species to be considered are those characteristic of such shallow waters.

c. *Safety factors.* The Act requires that the registration and labeling of pesticides be such as to prevent "unreasonable adverse effects to the environment." Accordingly, if a pesticide is to be classified for general use, the anticipated exposures to the formulated or use-diluted product resulting from handling and application typical of those practiced by untrained persons should fall short of the lethal exposures (LD_{50} or LC_{50}) by factors sufficiently large to ensure that risk of injury to man or nontarget wildlife is small or negligible. The margin of safety required to render a specific injury sufficently unlikely depends upon the type of exposure and upon the persons or animals most at risk. Each type of exposure and the corresponding safety factor must be considered separately.

(i) *A factor to allow for variations in exposure.* Studies of exposure during application, for example, show that the level of exposure depends on many factors, including environmental conditions (especially wind), the method and site of applications, the technique of the applicator, and the applicator's ability and willingness to wear prescribed protective clothing. These factors have been found to vary exposure levels 200–300 fold.[46] Exposure to children and wildlife is similarly expected to vary widely, depending on several factors. In practice, however, the figures and methods outlined in the previous section for estimating exposure levels resulting from typical uses have been derived from the high ranges of measured exposures. Hence, the calculation of exposure presented above refers to individuals exposed more intensely than average, and no additional safety factor is required to protect them.

(ii) *A factor to allow for individual variability and sensitivity in humans.* Studies of the absorption of pesticides through human skin, for example, have shown that the efficiency of dermal absorption varies widely from one part of the body to another and among individuals.[47] Feldman and Maibach have stated that "assuming a normal distribution 1 person in 10 will absorb twice the mean value while 1 in 20 will absorb 3 times this amount.[48] Accordingly, a safety factor of 3–5 would be required to protect a high percentage of individuals whose dermal absorption is greater than average.

In addition to variations in the efficiency of absorption, there are wide variations in the sensitivity of different individuals to a toxicant even under standardized conditions of exposure. This variability is expressed in the form of dose-response curves, which relate the percentage mortality within samples of exposed animals to the dose or concentration to which the animals are exposed. The steeper the slope of the dose-respone curve, the smaller the safety factor required to protect the more sensitive individuals, and *vice versa.*

In some cases the slopes of the dose-response curves are known. Gaines [49] has tabulated the acute oral and dermal toxicities of a large number of pesticides to rats, including in most cases estimates of both the LD_{50} (the dose required to kill 50 percent of a test group) and the LD_{01} (the dose required to kill 1 percent). For nearly all the chemicals, the ratio between the LD_{50} and the LD_{01} was between 2 and 4. Therefore the Agency has determined a safety factor of 3 below the LD_{50} is appropriate, since normally it will be sufficient to protect about 33 percent of a population of rats from acute poisoning. Since the human population is more variable in sensitivity than the strains of rats used in toxicity testing, somewhat larger safety factors would generally be required to provide comparable protection to humans.

(iii) *A factor to allow for variability and sensitivity among wildlife species.* Where the slope of the dose-response curve is unknown, as for many wildlife species, it may be estimated from measurements on comparable species or more generally from toxicological models. A widely used toxicological model is based on the empirical result that dose-response curves for many toxicants graph as straight lines over a wide range of doses when plotted on logarithmic-probability paper. The slope of the line varies according to the test organism and the nature of the toxicant. From a cross-section of existing dose-response data it has been estimated that a typical slope is 4.5 probits per log cycle, and a minimum slope about 2 probits per log cycle. The latter situation corresponds to a very variable test population with some individuals displaying high sensitivity to the toxicant. From this model it can be estimated that a dose or exposure 10 times lower than the LD_{50} or LC_{50} would be expected to lead to a mortality rate of about 0.01 percent under typical slope conditions, but to a mortality rate of 4 percent under minimum slope conditions. A dose-response 5 times lower than the LD_{50} or LC_{50} would be expected to lead to mortality rates of about 0.1 percent and 10 percent respectively. These figures are used as the basis for selecting a safety factor of 5–10 for setting the classification criteria for protecting wildlife. These factors would be expected to provide an ample margin of safety for a typical species, but only marginal protection to the most variable species. Even larger safety factors than 10 would be desirable to ensure protection of species in which even a single death is of special concern, for instance the death of an endangered species.

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[39] Lande, S. *An Epidemiological Study of Pesticide Exposure in Allegenky County, Pennsylvania,* 29 ARCH. ENVIRON. HEALTH 90 (1974); Gehlbach, S. H., W. A. Williams, J. S. Woodall and J. I. Freeman, *Pesticides and Human Health—An Epidemiological Approach,* 89 HEALTH SERVICES REPORTS 274 (1974).

[40] Studies also indicate significant portions of domestic pesticide users simply do not recognize the hazard that pesticides pose to children. For example, according to a study reported in the *Report of the Secretary's Commission on Pesticides and Their Relationship to Environmental Health* on the use of pesticides in one urban area it was found that many families ignored label direction warnings. "Locked storage was not employed by 88 percent of all families; 66 percent stored pesticides within easy reach of small children; 54 percent stored the chemicals near food or medicine; and 66 percent never wore protective gloves during use or washed their hands after application." *Supra* at 148. *See* also Baltimore, C. L., and R. J. Meyer, *A study of Storage, Child Behavioral Traits, and Mother's Knowledge of Toxicology in 52 Poisoned Families and 52 Comparison Families,* 42 PEDIATRICS 312 (1968).

[41] Jones, D. V. and C. R. Work, *Volume of a Swallow,* 102 AM. J. of DISEASES OF CHILDREN, 427 (1961).

[42] Lande, *supra.*

[43] *Id.*

[44] *Id.*

[45] Rudd, R. L. *Pesticides and the Living Landscape. supra.*

[46] Wolfe, *et al. supra* (1967).

[47] Maibach *et al. Regional Variation in Percutaneous Penetration in Man,* ARCH. ENVIRON. HEALTH 23, 208 (1971); Feldman and Maibach, *Percutaneous Penetration of Some Pesticides and Herbicides in Man,* TOXICOL. APPL. PHARMACOL. 126 (1974).

[48] Feldman and Maibach, *supra.*

[49] Gaines, T. B. *Acute Toxicity of Pesticides,* 14 TOXICOL. APPL. PHARMACOL. 515 (1969).

(iv) *A factor to allow differences on sensitivity between test animals and man.* A safety factor of 10 is commonly applied to extrapolate from test animals to man on the basis that the variability of human sensitivity is greater than the variability of test animal sensitivity. Where precise data are available on toxicity to humans—from accident records on presently registered products—the use of smaller factors may be justified.

d. *Selection of overall safety factors to prevent unreasonable adverse effects.* Each of the safety factors discussed above is individually desirable to protect against hazards posed by extreme and unusual exposure. However, if all the safety factors are applied independently, the process might simply serve to protect against extremes of extremes. It is impossible to devise criteria that could eliminate all hazards for pesticide use, and the statutory standard does not contemplate such stringent criteria. The criteria slected must provide aginst *unreasonable* adverse effects, not *all* adverse effects. Therefore, it is necessary to select safety criteria that will reduce the probability of injury to an acceptable level, considering the number of individual persons and the populations of important wildlife at significant risk, the probable frequency of sensitive individuals within the populations, and the probability of above-average exposure. Accordingly, safety factors between 3 and 10 have been used to provide protection against unreasonable adverse effects for the principal types of hazards discussed above. The precise safety factors used in setting numerical criteria, and the rationale for selecting them, are set forth in the next sections.

3. *Numerical Criteria for Use Classification.* a. *General numerical criteria for use classification.* The Administrator has determined that pesticide formulations which fall into Toxicity Categories III and IV will not generally cause unreasonable hazards if handled and used by untrained persons. In addition, pesticide formulations which fall into Toxicity Category II will generally not cause unreasonable adverse effects if used by the normally more skillful applicators who apply pesticides in nondomestic situations. However, for the reasons given above, the Administrator has determined that additional numerical criteria besides the toxicity categories of the formulated pesticide are needed to protect against certain adverse effects.

b. *Additional numerical criteria for use classification.* (i) *Acute oral toxicity.* As shown above, children may be expected to ingest, under certain conditions, pesticides stored or used in domestic situations at doses up to 0.5 g/kg. This is predicated on the assumption that the child gains access to the pesticide chemical mixture. If, however, the pesticide formulation is specially packaged in a container that is "child-resistant" in the sense that children under 5 years cannot normally gain access in a reasonable amount of time, the possibility of exposure is minimized. Accordingly, no criterion is given for acute oral LD_{50} on the formulated product. The Agency will be publishing regulations shortly, pursuant to the authority of section 25(c)(3) of the Act, concerning standards for packaging of the formulated pesticide product.

A criterion is provided in these regulations, however, to protect the child from ingestion of the product in domestic application sites after it has been diluted for use. Normally, the container in which a pesticide is held when diluted for use is accessible to children. A safety factor of 3 is applied to the 0.5 g/kg exposure figure. The resulting criterion is an acute oral LD_{50} of 1.5 g/kg on the product as diluted for use. The products that have an acute oral use dilution LD_{50} below this figure will be candidates for restricted use classification.[illegible] A relatively low safety factor of 3 is justified because accident data can be used to supplement toxicity criteria in identifying product uses that should be classified for restricted use.

(ii) *Acute dermal toxicity.* As shown above, applicators and others may be exposed to doses of the use-diluted pesticide in spray or mist formulations as high as 16 g/kg/day, when the pesticides are applied by unskilled or careless applicators. Since the exposure an unskilled applicator may experience is known from the field studies conducted by Wolfe *et al.*, a precise LD_{50} criterion can be selected to adequately protect applicators receiving such exposure levels. Applying the minimum safety factor of 3 to an acute dermal LD_{50} of 16 g/kg/day would result in an LD value of 48 g/kg/day. However, LD_{50} values and LD values are based on experimental animal exposure of 24 hours. Since applicators normally are only exposed up to a maximum of 8 hours, using experimental data based on a continuous 24 hour exposure employs a safety factor to protect humans who are only exposed for ⅓ the time. Moreover, Durham, *et al.*, has shown that bathing after exposure results in a rapid decrease in dermal absorption of pesticides. Therefore, since the percent of pesticide dermally absorbed is partially a function of time the actual absorption of the pesticide may be much less than the indicated dermal exposure if the applicator washes after application.[illegible] Accordingly, an acute dermal LD_{50} criterion of 16 g/kg/day has been selected; it takes into account an approximate safety factor of three.

A safety factor of 3 is justified by the following considerations: (a) the safety factor is applied to the high range of exposure values measured in actual field studies; (b) accident data can be utilized to supplement numerical criteria to identify pesticides whose use should be restricted. However, a safety factor lower than 3 would not be appropriate since measurements of actual exposure in the field indicate that toxic doses may be approached under conditions of widespread and commonly recognized practice of use.

For reasons stated above, this criterion is applied only to pesticides used in nondomestic situations. Although domestic indoor applications at times may involve intense exposures, this fact is more than offset by the short periods of indoor exposure normally experienced by non-professional applicators. The dermal and inhalation toxicity criteria of the Toxicity Categorization Scheme are sufficient to protect unskilled persons exposed indoors against acute effects of pesticides in Categories III or IV.

(iii) *Hazards to terrestrial wildlife.* The principal hazard to terrestrial wildlife occurs from contamination of their food with pesticides. To afford a measure of protection for mammalian species, pesticides intended for outdoor use which result in residues exceeding one-fifth of

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[illegible] Because it is difficult to measure the toxicity of materials at very high doses, the Guidelines as currently proposed specify that numerical toxicity measures are not required if the oral or dermal LD_{50} exceed 5 g/kg. For the purpose of determining whether a product meets the numerical criteria derived in this section, it will be permissible to estimate the LD_{50} of a pesticide product from measurements of toxicity made of higher concentrations. For example, the LD_{50} of a product as diluted for use may be estimated as XY, where X is the LD_{50} of the formulated product and Y is the factor by which the formulation is diluted for use. In cases where the LD_{50} of the formulated product exceeds 5 g/kg, its toxicity may be estimated in the corresponding way from the LD_{50} of the active ingredient.

[illegible] Durham, E. F. Wolfe, HR., and Elliot, J. W. *Absorption and Excretion of Parathion by Spraymen*, 24 ARCH. ENVIRON. HEALTH, 381 (1972).

the acute oral LD_{50} will be candidates for restricted use. The Agency realizes that certain situations exist in which the subacute dietary LC_{50} may be a more appropriate standard of mammalian toxicity. However, given the difficulties in obtaining such data for meaningful mammalian indicator species the criterion employs the more readily obtainable acute oral LD_{50}. Acceptable protocols for obtaining subacute dietary LC_{50} data are available, however, to represent toxicity[58] to avian species. Accordingly, pesticides intended for outdoor use which result in residues exceeding one-fifth of the subacute dietary LC_{50} will also be candidates for restricted use. The criteria also specify that the residues are to be computed immediately after application, the time of maximum residues. Since these residues may degrade over time, an additional safety factor is thereby incorporated.

The choice of a slightly higher safety factor for aquatic wildlife than for terrestrial wildlife is based on the fact that birds and mammals, unlike aquatic wildlife, have the ability to at least partially limit their exposure to pesticides by moving out of treated areas or by switching to alternative foods; moreover, some animals cease feeding when they start to experience toxic symptoms.

(iv) *Hazards to aquatic organisms.* The principle hazard to aquatic organisms occurs when pesticides are applied directly to shallow water, especially when applied by unskilled persons in contravention of label directions for use and precautionary statements. A measure of the likely exposure is the average concentration of the pesticide when applied to a water body 6 inches deep. A safety factor of 5 would provide an adequate margin of safety for all but the most sensitive species; an additional factor of 2 is applied since unlike terrestrial wildlife, acquatic organisms, have no means of escaping from the toxicant. Accordingly, pesticides intended for outdoor use which result in concentrations in shallow water exceeding 1/10 the acute LC_{50} for species likely to be exposed will be candidates for restricted use.

4. *Numerical Criteria for Rebuttable Presumption Against Registration or Reregistration.* Besides deriving acute toxicity criteria for initially determining whether a pesticide should be classified for restricted or general use, acute toxicity criteria have also been derived for initially determining whether a pesticide should be registered or denied initial or continued registration. The same considerations of estimated exposure discussed above have been applied in deriving these criteria; however, estimates of exposure are based on the assumption that such highly toxic pesticides will be classified for restricted use and therefore be limited to use by skilled, competent applicators.

(1) *Acute Oral Toxicity.* No acute oral toxicity criterion is included for determining a rebuttable presumption against registration. Such a criterion was included in the proposed regulation [§ 162.11(b)(2)(i)(D)] and was the subject of a number of comments. The Agency has concluded that trained, competent applicators will be able to minimize the hazards to children by adhering to general safety procedures and specific label directions for use. If based upon the use and accident history data of the product, or similar products, the Administrator determines that even when used by trained applicators the pesticide causes or will cause unreasonable adverse effects on man or the environment, the pesticide will be denied registration or cancelled in accordance with § 162.11(a)(6) of these regulations.

(2) *Dermal Toxicity Criteria.* All pesticides in Toxicity Category I will be candidates for restricted use classification and unless it is shown that the risk from use of the pesticide is not as great as indicated by this criteria for risk, use of the pesticide will be restricted to certified applicators. Yet as the literature cited above indicates, even skilled applicators may receive potentially lethal exposure to the highly concentrated and toxic formulated pesticide and to the use-diluted pesticide. Accordingly, acute dermal toxicity criteria for both the formulated and use-diluted pesticide are included to determine if there is a rebuttable presumption against initial or continued registration. For the formulated product, a criterion of an acute dermal LC_{50} of 40 mg/kg or less has been selected. Products meeting this criterion have an LD_{50} that is 1/5th that of the LD_{50} of the non-domestic use pesticides, and 1/25th that of the LD_{50} of the domestic use pesticide initially classified for restricted use because of dermal toxicity. Clearly, the margin of safe exposure for such pesticides is extremely small and such pesticides must receive particular scrutiny before the Administrator can determine that the pesticide will not generally cause unreasonable adverse effects.[59]

An acute dermal LC_{50} of 6/g/kg criterion for the use-dilution of pesticides formulated as a mist or spray, has been selected to give rise to a rebuttable presumption against registration based upon the results of the Wolfe, *et al.*, exposure studies discussed above which indicated the anticipated dermal exposure to skilled applicators. These studies show that even a skilled applicator can experience up to 6 g/kg/day of exposure to the use diluted product. For the same reasons discussed above in the explanation of the dermal classification criterion, this criterion incorporates a safety factor of 3.

(3) *Inhalation Toxicity Criterion.* An inhalation toxicity criterion of an LC_{50} of 0.40 mg/l or less has been selected to give rise to a rebuttable presumption against registration. Pesticides meeting this criterion have an LC_{50} that is 1/5th the LC_{50} of the non-domestic use pesticides which are candidates for restricted use because of inhalation toxicity.

(4) *Wildlife Toxicity Criteria.* Based upon the considerations discussed in the determination of classification criteria, the following criteria have been selected to safeguard wildlife by giving rise to a rebuttable presumption against registration:

If a pesticide's ingredient(s), metabolite(s), or degradation product(s):

(1) Occurs as a residue immediately following application in or on the feed of a mammalian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species, at levels equal to or greater than the acute oral LD_{50} measured in mammalian test animals as specified in the Registration Guidelines.

(2) Occurs as a residue immediately following application in or on avian feed of an avian species representative of the species likely to be exposed to such feed in amounts equivalent to the average daily intake of such representative species at levels equal to or greater than the subacute dietary LC_{50} measured in avian test animals as specified in the Registration Guidelines.

(3) Results in a maximum calculated concentration following direct application to a 6-inch layer of water more than ½ the acute LC_{50} for aquatic organisms representative of the organisms likely to be exposed as measured on test animals specified in the Registration Guidelines.

Pesticides which meet the criteria for avian and mammalian feed residues would cause an estimated 50% mortality among exposed populations; pesticides which meet the criteria for the protection of aquatic organisms would cause an estimated 15–20% mortality among exposed populations. Pesticides which will result in such toxic levels and severe mortality rates on exposed wildlife populations obviously must be closely scrutinized before registration is approved and used under stringent restrictions.

D. *Chronic Toxicity Criteria.* In addition to the acute effects from a single exposure to pesticides, a determination of "unreasonable adverse effects on the environment" must include an analysis of any chronic effects which may result from exposure to a pesticide. Accordingly, criteria for determining chronic effects for registration and classification are set forth in §§ 162.11(a) and 162.11(c). Several commenters questioned the inclusion of these criteria in the proposed regulation and their individual basis for selection. Therefore, each of the criteria contained in the final regulation and their basis are set forth below including discussion of any modifications to the criteria contained in the proposed regulation.

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[58] If a pesticide causes significant *chronic* toxic effects on wildlife species or on man, it is subject to classification for restricted use under another criterion.

[59] The United States Department of Transportation and the United Nations also have developed numerical acute toxicity criteria to determine "extremely toxic" material. The Department of Transportation specifies as extremely toxic, material with an acute dermal LD_{50} of 20 mg/kg or less, which closely approximates the Agency's criteria of 40 mg/kg. The United Nations has established a criterion identical to the Agency's to indicate especially toxic pesticides.

1. *Screening Criteria for Classification.* The chronic effects criteria which indicate as an initial matter that the pesticide will be classified for restricted use are qualitative in nature. Chronic toxicity effects cannot easily be evaluated on a comparative quantitative scale, as can the acute toxicity LD$_{50}$ and LC$_{50}$ values. Chronic effects by definition are those caused by repeated and prolonged exposure. The chronic hazard of a pesticide is, moreover, a function of its chemical and environmental characteristics such as persistence, mobility, and potential for biomagnification in food chains, and bioaccumulation in human tissue. Humans and other organisms will generally be exposed to pesticides which are highly persistent, mobile and bioaccumulative. The major issue regarding pesticides with these properties is whether the pesticide should be registered. Classification of a pesticide use as restricted in all likelihood will not reduce the threat of exposure to large populations. Accordingly, while § 162.11(c) authorizes the classification decision to be based on an evaluation of chronic toxicity effects, such pesticides will be classified as restricted use only where restriction of use to a certified applicator could be anticipated to limit the exposure or where a regulation could be promulgated pursuant to § 162.11(c) (5) with restrictions to control the exposure.

2. *Screening Criteria for Rebuttable Presumption.* Section 162.11(a) (3) (ii) sets forth three basic risk criteria for the determination of chronic effects which if met or exceeded by "a pesticide's ingredient(s), metabolite(s), or degradation product(s)," give rise to a rebuttable presumption against registration or continued registration. Section 162.11(a) (3) (ii) (A) provides that such a presumption shall arise for any pesticide which induces "oncogenic effects in experimental mammalian species or in man as a result of oral, inhalation, or dermal exposure; or induces mutagenic effects, as determined by multitest evidence." With respect to oncogenic effects, this criterion incorporates the policy and principles established in the DDT cancellation proceeding and the Aldrin/Dieldrin suspension proceeding.

Positive oncogenic effects in man would obviously trigger very serious scrutiny. However, as noted above, such results are rarely available because of the long latency period of tumor induction, because of frequently encountered widespread contamination which makes it impossible to establish an uncontaminated control group and because of the ethical and legal problems associated with conducting cancer research on humans.[34] Because of the difficulties of obtaining reliable human cancer data, the oncogenic criterion refers to positive oncogenic effects in man or "in experimental mammalian species." The use of animal test data to evaluate human cancer risks has been widely accepted by the scientific community and by public policy-making agencies. Moreover, such data are particularly appropriate because the relatively short life span of test animals allows for testing for the entire latency period and because of our relatively well-developed understanding of the pathological development of tumors in mice and rats. When compared to the millions of people who may be exposed to the pesticide, the number of animals used in oncogenic tests is extremely small. As in the case of acute toxicity testing, the variability of human response to carcinogens is generally greater than that of the test animals. Accordingly, as noted above, a positive oncogenic effect in any test animal is sufficient to characterize the pesticide as posing a cancer risk to man. By the same reasoning, negative results from oncogenic animal tests have only limited significance and thus should normally be superseded by positive results. The number and sensitivity of the test animals as compared to the general human population are the principal reasons for this limited utility.[35]

The Administrator in his Aldrin/Dieldrin suspension order also specifically concluded that because of these inherent limitations of animal testing "a substance that will induce cancer in experimental animals at any dose level, no matter how high or low, should be treated with great caution."[36] The Court of Appeals unanimously affirmed this finding. As noted above, negative results are of limited value and although a no-effect level may theoretically exist, it is frequently impossible to establish with sufficient confidence to justify sanctioning widespread human exposure.[37]

Moreover as an additional outgrowth of the Aldrin/Dieldrin proceedings and as explained previously in the discussion of § 162.3(bb), the term "oncogenic" is used in the regulations because the Administrator had determined that the distinction between "benign" and "malignant" tumors is not meaningful in determining the hazard of cancer to man on the basis of tests conducted on a laboratory species, given the "increasing evidence that many tumors can develop into cancers." He has determined that "for purposes of carcinogenicity testing, they should be considered synonymous."[38]

In making the determination that the rebuttable presumption is activated because of a finding of chronic effects, the Agency will take into consideration the type of effect, the statistical significance of the findings and whether the tests were conducted in accordance with the material requirements for valid tests as recognized by experts in the field. Where testing produces positive chronic effects but such effects are not statistically significant or such tests were not conducted in accordance with the material requirements for valid tests as recognized by experts in the field, additional statistical analysis, histological or other pathological review, or testing may be required even though the rebuttable presumption may not have been triggered by the initial test results.

While neither the DDT cancellation proceeding nor the Aldrin/Dieldrin suspension proceeding considered the hazards to man from exposure to mutagenic substances, governmental agencies and scientific groups which are currently weighing the hazards of introducing potentially mutagenic substances into the environment stress the inherent risk to man.[39] Furthermore, on the basis of tests on microbial systems, there is increasing evidence indicating a correlation between carcinogenesis and mutagenesis.[40] At this time without additional corroborative evidence, however, there is no single animal test protocol which has been demonstrated as a sufficiently reliable indicator of a substance's mutagenic hazard to man to give rise to a rebuttable presumption against registration or continued registration. Therefore, the mutagenic criterion requires a showing of positive results in more than one test system before regulatory action, other than requiring additional testing, can be justified. The Guidelines for registering pesticides set forth the conditions under which mutagenic testing is required and the Appendix to the Guidelines sets forth acceptable test protocols.

It is not the policy of EPA to ban all pesticides which produce oncogenic or mutagenic effects. Rather, the cost of control, the levels of exposure, and the benefits of use must also be taken in account in any final regulatory decision. This Section 162.11 establishes a framework for arriving at these decisions with a full opportunity for the public and other interested parties to participate.

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[34] *See* Consolidated DDT Hearings, Opinion and Order of the Administrator 37 FR 13369, 13371; Shell Chemical Company, *et al.*, Findings of Fact and Conclusions (FIFRA Dockets No. 145 etc.), 39 FR 37249, 37252, 37254; Opinion and Order of the Administrator on Suspension of Aldrin-Dieldrin, 39 FR 37265, 37270; *EDF v. EPA* 510 F. 2d at 1299; Supplemental Statement of Reasons for Denial—State of Louisiana Request for Emergency Use of DDT on Cotton, 40 FR 15949, 15950.

[35] See generally, Consolidated DDT Hearings, Opinion and Order of the Administrator; 37 FR at 13371; Shell Chemical Company, *et al.* Findings of Fact and Conclusions, 39 FR at 37252, 37254; Shell Chemical Company, *et al.* Opinion of the Administrator, 39 FR at 37269–70; *EDF v. EPA*, 510 F. 2d at 1299; Statement of Reasons and Supplemental Statement of Reasons for Denial—State of Louisiana Request for Emergency Use of DDT on Cotton, 40 FR at 15940, 15950.

[36] Administrator's Aldrin/Dieldrin Findings, 39 FR at 37268.

[37] This view was mirrored in the recently published "Report of the Committee for Working Conference on Principles of Protocols for Evaluating Chemicals in the Environment." "[The term no-effect level] is statistically meaningless and therefore of limited value since it merely means that no effect was observed in studies using a group of animals of particular size. Such an observation is completely compatible with the presence of an adverse effect, which in further studies with larger sample sizes or with different types of observation might lead to a positive outcome." Environmental Studies Board National Academy of Engineering and Committee on Toxicology, National Research Council, *Principles for Evaluating Chemicals in the Environment*, (1975).

[38] Administrator's Aldrin/Dieldrin Findings, 39 FR at 37267 (October 18, 1974); *EDF v. EPA*, 510 F. 2d at 1300 (D.C. Cir. 1975).

[39] *Principles for Evaluating Chemicals in the Environment, supra; The Testing of Chemicals for Carcinogenicity, Mutagenicity, Teratogenicity*, published by the Minister of Health and Welfare, Canada (September, 1973); and *Environmental Mutagenic Hazards*, 187 SCIENCE 503 (1975).

[40] *Principles, supra*, at 147.

The second criterion for chronic effects set forth in § 162.11(a) (3) (ii) (B) provides that a rebuttable presumption shall arise if a substance "produces any other chronic or delayed toxic effect in test animals, at any dosage up to a level, as determined by the Administrator, which is substantially higher than that to which humans can reasonably be anticipated to be exposed, taking into account ample margins of safety." The dosage to be tested will be specified in the Registration Guidelines. In determining the levels at which positive test results will give rise to a rebuttable presumption the Administrator must take into account ample margins of safety and evaluate among other things: the statistical reliability of the test data, the degree of varying sensitivity estimated for exposed populations, and the nature of the chronic effect produced. Chemicals have been found to produce deleterious effects after prolonged and repeated exposure to many organs and functions of the body including the lungs, central nervous system, hematopoietic system, metabolism, kidneys, reproductive systems and others. Therefore, if adverse effects of such a nature will be produced by exposure to a pesticide at any level up to a level exceeding possible human exposure taking into account ample margins of safety, it is appropriate that the regulations provide a rebuttable presumption against registration or continued registration of the pesticide. The pesticide's potential for producing such effects is determined from studies required pursuant to § 162.8 of these regulations, the Guidelines, and the Appendix to the Guidelines, or other test evidence available to the Agency.

The proposed regulation also provided that a presumption against registration would arise if evidence of teratogenic potential was found, irrespective of level of exposure in test animals. However, the Agency has determined with respect to teratogenic effects, that the dose at which the effect was observed in experimental animals and the dose to which humans may be exposed must be considered before a rebuttable presumption against registration arises. Therefore, evaluation for teratogenic effect is incorporated in the criterion at § 162.11(a) (3) (ii) (B).

The final criterion set forth in § 162.11 (a) (3) (ii) (C) establishes a criterion to protect against significant reductions in local, regional, or national populations of non-target organisms or fatality to members of endangered species. In the DDT cancellation decision, the Administrator found that DDT can reasonably be anticipated to result in such chronic effects on non-target organisms and included that finding as a major basis for cancellation.

E. *Emergency Treatment.* Section 2(q) (2) (D) (iii) of the Act provides that any pesticide which is "highly toxic to man" is misbranded unless the label bears "a statement of a practical treatment (first aid or otherwise) in case of poisoning by the pesticide."[*] Accordingly, where there is no practical treatment in the case of poisoning by the pesticide, a rebuttable presumption against registration or continued registration shall arise. In such an instance, there would be a serious question as to the legality of registering the product.

The language of the criterion of § 162.11(a) (3) (iii) has been modified to clarify that an emergency treatment statement is only required for treatment of acute poisonings from a single exposure.

F. *Rebuttal of Screening Criteria for Use Classification and Presumption Against Registration.* As is discussed above, the criteria set forth in §§ 162.11 (a) (3) and 162.11(c) (1) and (2) are intended as screening mechanisms to determine as an initial matter which pesticides are subject to a presumption against registration and which pesticides are candidates for restricted use classification respectively.

The final decision regarding the registrability of a product and its use classification is made only after consideration of the risks and benefits of use of the pesticide as proposed to be registered. The criteria of these sections are indicators of potential hazard. The applicant or registrant, as the case may be, may establish to the Agency's satisfaction that the hazard anticipated by the acute or chronic screening criteria will not in fact occur. The regulations set forth the elements which the applicant or registrant must demonstrate to rebut the presumption of the screening criteria.

1. *Classification.* One of the decisions in determining whether an acutely toxic pesticide should be restricted to use by or under the direct supervision of certified applicators is whether label instructions standing alone will be adequate to prevent the hazards associated with use. Accordingly, the regulation at § 162.11(c) (3) sets forth the criteria that will be evaluated in determining the adequacy of the label and labeling to prevent unreasonable adverse effects on the environment. These criteria include an evaluation of: (1) the complexity of required operations or procedures and the need for specialized training or experience; (2) the safe margin of error associated with the use; (3) the "widespread and commonly recognized"[*] use practice; (4) the need for "specialized apparatus, protective equipment or material" normally not available to the general public; and (5) the effect of failure to follow directions for use in causing delayed or chronic adverse effects. Furthermore, the use and accident history of a pesticide or a similar pesticide will bear on the evaluation and application of these criteria to the classification decision of a particular pesticide. These criteria were contained in the proposed regulations and have not been modified. They were selected as representing the factors that would determine the degree that an unskilled applicator could be expected to follow label directions for use and required safety procedures. They require a weighing of the complexity of use of a pesticide in accordance with label instructions, the likelihood that instructions commonly will be followed, and the adverse effects likely to result if the label instructions are not followed. Secondly, the applicant or registrant may submit data or arguments challenging the finding of the Agency that the criteria have been met or may be able to establish that the formulation, packaging or method of use of the product is such as to eliminate the hazardous route of exposure. For example, a pesticide which meets the criteria for restricted use classification on the basis of dermal risk may be marketed as a granular formulation rather than as a liquid formulation and thereby reduce the hazards of dermal exposure. So too, if the formulation of the pesticide is extremely toxic while its use dilution is not, the pesticide may be packaged as a "closed system" to prevent hazardous exposure during mixing. And fourthly, the applicant or registrant may demonstrate that the benefits from unrestricted use of the pesticide outweigh the risks of unrestricted use of the pesticide. All these determinations are in accordance with the statutory mandate of section 3(d) of the Act, that the Administrator determine whether general use classification of the pesticide will cause "unreasonable adverse effects on the environment."

In addition to the screening criteria, § 162.11(c) (4) provides that "if the Agency determines that based on human toxicological data, use history, accident data, monitoring data, or such other evidence as the Administrator identifies, the product use(s) may pose a serious hazard to man or the environment, which can be prevented by classification for restricted use," the use will be classified restricted. Thus, although based on the screening criteria a pesticide would be a candidate for general use classification, it could be classified for restricted use on the basis of other evidence available to the Administrator.

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[*] A registered pesticide which is misbranded is in violation of section 8(b) and must be cancelled; an application for a new registration must be denied pursuant to section 3(c) (5) and (6) if "its labeling and other material required to be submitted [do not] comply with the requirements of this Act."

[*] This language has been interpreted by the Eighth Circuit Court of Appeals to mean the uses and practices commonly followed which are not approved on the label and labeling. *Southern National Manufacturing Co. Inc. v. Environmental Protection Agency*, 470 F. 2d 194 (1972).

Finally, as part of the classification determination, § 162.11(c) (5) provides that any product use classified for restricted use and limited to application by or under the direct supervision of a certified applicator may "additionally or alternatively" have other restrictions imposed by regulation. A commenter argued that the "other restrictions" authorized by section 3(d) (1) (C) (ii) of the Act and provided for by this Section of the regulations can be imposed only in lieu of, not in addition to, a certified applicator restriction. However, such an interpretation conflicts with the legislative history of this provision. "Section 3(d) (1) (C) (ii) establishes a system to assure a full and fair consideration of alternative or additional restrictions which the Administrator may wish to impose." Senate Agriculture Committee Report, at 21. The restrictions cited in the regulation are intended merely as examples of the type of restrictions which may be imposed under this authority.

2. *Presumption Against Registration or Continued Registration.* As explained above, a rebuttable presumption arises against registration or continued registration of any pesticide which meets or exceeds the criteria for risk of § 162.11 (a) (3). When the presumption arises, the party seeking new or continued registration may rebut the presumption by sustaining an affirmative burden of proof specified in the regulations. In response to comments, the Agency has elaborated on how the rebuttable presumption will be applied. Accordingly, § 162.11 has been modified to specify the procedures, methods and criteria for rebuttal of a presumption against registration or continued registration.

The regulations provide that upon a determination that a pesticide meets or exceeds the criteria for risk § 162.11 (a) (3), the Administrator shall issue notice to the applicant or registrant of the pesticide of this determination and state that the applicant or registrant has the opportunity to submit evidence in rebuttal of the presumption in accordance with the provisions of § 162.11(a) (4). The Agency will consider comments received from all interested parties regarding rebuttal of the presumption against registration. The burden of proof, however, rests with the applicant or registrant of the pesticide product, as the case may be. Section 162.11(a) (4) provides that "the party seeking new or continued registration may rebut the presumption by sustaining the burden of proving:

(i) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraphs (3) (i), or (iii), that when considered with the formulation, packaging, method of use, and proposed restrictions on and directions for use and widespread and commonly recognized practices of use, the anticipated exposure to an applicator or user and to local, regional or national populations of nontarget organisms is not likely to result in any significant acute adverse effects; or

(ii) In the case of a pesticide which meets or exceeds the criteria for risk set forth in paragraph (3) (ii), that when considered with proposed restrictions on use and widespread and commonly recognized practices of use, the pesticide will not concentrate, persist or accrue to levels in man or the environment likely to result in any significant chronic adverse effects."

(iii) That the determination by the Agency that the pesticide meets or exceeds any of the criteria for risk was in error.

These provisions for rebuttal of a presumption against registration permit submission and consideration of evidence to show that the levels of exposure necessary to cause an identified acute, subacute or chronic effect will not result from use of the pesticide. As in the case of rebuttal of the initial determination that a pesticide use should be classified for restricted use, it may be possible to show that the initial determination of the Agency that the pesticide met or exceeded the criteria for risk was in error or that the formulation, packaging, method of use, directions for use, or label and labeling are adequate to prevent the hazards from use of the pesticide. In the case of the pending reregistration of a pesticide product, in particular, evidence as to the use and accident history of the pesticide, or a similar pesticide, will be carefully considered in the evaluation of acute risk. In addition, in the case of a presumption against registration on the basis of chronic toxicity, it may be shown, for example, that the chemical characteristics of the pesticide are such that it has a very short half-life and that exposure will not occur or that the pesticide is not mobile in the environment and will not concentrate and bioaccumulate in man or other organisms. With respect to a pesticide which meets the criteria for risk set forth in paragraph (a) (3) (ii) (A) (oncogenic or mutagenic effects), the presumption may be rebutted by showing that use of the pesticide will not result in residues of the pesticide's ingredient(s), metabolite(s) or degradation product(s) in man, in food or in media other than food to which significant portions of the human population are exposed. This is in keeping with the principle established by the Administrator and affirmed in court decisions that it is virtually impossible to establish a no effect level for oncogenic compounds. The Agency has determined that similar reasoning applies to mutagens. Similarly, the rebuttal opportunity is not intended to permit rebuttal of the presumption when triggered by oncogenic or mutagenic effects solely because of a negative response in test animals at a different or lower dose level or through evidence that a tolerance has been established for the pesticide's ingredient(s), metabolite(s) or degradation product(s). In the case of either acute or chronic hazard, moreover, it may be shown that the risks from use of the pesticide can be minimized and brought within acceptable limits by restrictions on use, as for example, restriction to use by or under the direct supervision of a certified applicator or in accordance with any other regulatory restrictions imposed pursuant to section 3(d) (1) (C) (ii) of the Act. In summary, the rebuttal considerations take into account the individual characteristics of the pesticide and evaluate the potential hazard after consideration of the likelihood that exposure will result from use of the pesticide as proposed to be registered.

If the Administrator determines that the presumption against registration has been rebutted, in accordance with § 162.11(a) (4), and that the pesticide otherwise complies with the requirements of the Act and these regulations, he shall register the pesticide or continue any registration already in effect. In the case of an application for registration for which notice of approval is published, pursuant to § 162.7(d) (2) of the regulations, such notice shall state the Administrator's determination and supporting findings that the presumption has been rebutted.

If an applicant or registrant fails to rebut the presumption, the regulations provide that a notice initiating final determination of cancellation or denial of registration must issue. This is in accordance with the court decisions and statutory requirements which provide, as discussed above, that the notice must issue where a substantial question of safety is determined to exist. Failure to rebut the presumption establishes that such a substantial question exists.

Although a formal notice must issue following the determination that the presumption has not been rebutted, the statute provides some flexibility in the type of notice to be issued. For instance, under Section 6, the Administrator may issue a notice of intent to cancel registration pursuant to section 6(b) (1), and the registrant is entitled to request a formal adjudicatory hearing following receipt of the notice. Or pursuant to section 6(b) (2), he may issue a notice of intent to hold a hearing "to determine whether or not [the pesticide's] registration should be cancelled * * *." The legislative history makes it clear that the purpose for including the section 6(b) (2) notice procedure was to permit "the Administrator to initiate formal review without placing a stigma on a product when he is not convinced that the registration should be cancelled." Senate Committee on Agriculture and Forestry, S. Rep. No. 92–838, 92nd Cong. 2d Sess. 12–13 (1972).

Where a substantial question of safety exists with respect to a pesticide, the only circumstance in which the Administrator may not be convinced that cancellation should occur is where he may have reason to believe the benefits outweigh the established risks. Accordingly, the regulations provide that in determining whether to issue a notice of intent to cancel (section 6(b) (1)) or a notice of intent to hold a hearing (section 6(b) (2)), the Administrator may take into account a preliminary staff recommendation as to the balance of risks and benefits. Based on a recommendation that benefits appear to outweigh the risk, the Administrator may decide to issue a section 6(b) (2) notice and thereby initiate a formal adjudicatory hearing where the benefit/risk balance could be fully considered in the public forum for purposes of making a final determination as to cancellation, without any stigma which may be associated with a section 6(b) (1) hearing. In order to aid in the preliminary staff recommendation as to benefits, the regulations permit the registrant to submit evidence as to benefits at the same time as he undertakes to rebut the presumption against continued registration under the specified risk criteria.

Similarly, with respect to denials of registration, the regulations provide for issuance of a notice of denial pursuant to section 3(c) (6), upon the determination that the applicant has failed to rebut the presumption as to risk. The applicant may then request a hearing which would correspond to the hearing under section 6(b) (1). Based on a preliminary staff recommendation that benefits appear to outweigh risks, the Administrator may decide, as provided in the regulations to issue a notice of intent to hold a formal adjudicatory hearing similar to a section 6(b) (2) proceeding. The authority for the regulations to provide for this corresponding section 6(b) (2) proceeding for denials of registrations rests on the general authority of sections 25 (a), 21 and 6 of the Act.

The foregoing procedures preserve the requirements established by courts and the Act that weighing of risks and benefits may not interfere with initiation of the formal administrative process, where a substantial question of safety exists, and yet provides the flexibility necessary for informed, fair and open Agency decisions.

Finally, the regulations set forth the burden of proof and issues to be considered at a hearing. In addition to the issues relating to safety considered prior to issuance of the notice, the balance of risks and benefits is the third issue to be considered by the Administrative Law Judge in the hearing. In hearings following issuance of notice pursuant to sections 3(c) (6), and 6(b) (1), the burden of proof as to all issues rests squarely with the applicant or registrant, as the case may be. If the hearing is a section 6(b) (2) proceeding or the equivalent for denials of registration, the burden of proof as to risks rests with the applicant or registrant. The Agency will put into evidence the preliminary staff recommendations as to benefits, and all other evidence from the parties to the proceeding will be considered in arriving at a final determination as to whether benefits exceed risks.

The regulation provides for the withdrawal of the notice of intent to hold a hearing prior to the commencement of the hearing if the Administrator determines that there is "insufficient public interest in the proceeding to warrant holding the hearing or that it would not otherwise serve the public welfare." As a general rule EPA plans to withdraw the notice if the preliminary staff recommendation or subsequent Agency investigation indicates that the benefits from use of the pesticide outweigh the risks *and if* there is no party willing to participate in the hearing who will argue against registration of the pesticide. EPA will follow this general rule so as not to misuse scarce Agency resources or subject registrants to the unnecessary expense of hearings in which all the parties agree that the pesticide should be registered.

With respect to the final risk/benefit determination under any of the foregoing procedures, the statute, the legislative history, and judicial interpretations recognize that the Administrator may find that the benefits of use outweigh the risks even where this risk is determined to pose a substantial question of safety. Moreover, in striking the balance, certain risks and certain benefits must be given more weight than others. As the court stated in *EDF v. Ruckelshaus, supra:*

> The process is a delicate one in which greater weight should be accorded the value of a pesticide for the control of disease, and less weight should be accorded its value for the protection of a commercial crop. 439 F. 2d at 594.

Section 162.14 *Forms of plant and Animal Life and Viruses declared to pests.* Section 25(c) (1) of the Act authorizes the Administrator to declare as a pest all forms of plant and animal life (other than man and other than bacteria, viruses and other microorganisms in or on living man or other living animals) which are injurious to man or the environment. In response to comment the language of § 162.14(b) has been modified to clarify those pests which come within the scope of amended FIFRA.

Section 162.15 *Devices Subject to the Act.* Section 25(c) (4) of the Act authorizes the Administrator to specify those devices which are subject to the provisions of paragraph 2(q) (1) or section 7 of the Act. The proposed regulations at § 162.3(ff) (1) and (4) had declared certain devices subject to the Act. For purposes of clarity and thoroughness, a new § 162.15 has been added to these regulations to specify in detail those devices which fall within the purview of amended FIFRA. The Agency realizes that certain instruments and contrivances are marketed in conjunction with a pesticide; in these cases such products will be considered as pesticides rather than as devices. Devices deemed to be subject to the Act include, but are not limited to, instruments for the purpose of trapping, destroying, repelling or otherwise mitigating any form of plant or animal life and viruses declared to be pests at § 162.14, except those instruments which the Administrator determines either (1) to be adequately regulated by another Federal Agency, or (2) to be of a character which is unnecessary to be subject to this Act in order to carry out the purposes of this Act.

Instruments of a character unnecessary to be subject to this Act include (1) those which depend for their effectiveness more upon the performance of the person using the device than on the performance of the device itself, and (2) those which operate to entrap vertebrate animals. Products generally falling within these two categories include rat and mouse traps, fly swatters, tillage equipment for weed control and fish traps.

Instruments declared to be devices subject to § 2(q) (1) and section 7 of this Act include but are not limited to: (A) certain ultraviolet light systems, ozone generators, water filters and air filters (except those containing substances or mixtures of substances which are pesticides), and ultrasonic devices, for which claims are made to kill, inactivate, entrap, or suppress the growth of fungi, bacteria, or viruses in various sites; (B) certain high frequency sound generators, carbide cannons, foils, and rotating devices, for which claims are made to repel birds; (C) black light traps, fly traps, electronic and heat screens, fly ribbons, and fly paper, for which claims are made to kill or entrap certain insects; and (D) mole thumpers, sound repellents, foils, and rotating devices, for which claims are made to repel certain mammals. The Administrator will designate such provisions of paragraph 2(q) (1) and section 7 of the Act to be applicable to devices as he finds necessary to effectuate the purposes of the Act.

Section 162.17 [§ 162.16] *Registration Requirement for Intrastate Products.* This section of the regulations has been rewritten to clarify the language and incorporate much of the enforcement policy that appeared in the preamble of the regulations as proposed. The applicant for registration must comply with the data requirements for new registration provided however that the requirement for efficacy data may be waived on the basis of the recommendation of a State agricultural experimental Station or other Federal or State agency authorized by law to conduct pesticide research. In addition, the Administrator may initiate the waiver of other data requirements, in accordance with the standard of § 162.8(a) (3), in his notice to the applicant to submit a full application for federal registration. To ease the transition from State to Federal registration, these applications will be handled in a group of like products rather than as individual products. If the applicant complies with the procedures of this section, pending the final registration decision, either approving or denying the registration application, he may continue to sell or distribute the product solely within intrastate commerce subject to the requirements of paragraph (f) of this section. This policy is in accordance with section 3(c) (2) of the Act.

Section 162.21 [§ 162.15] *Rules concerning certain pesticides.* This section is intended as an open-ended section to include regulations the Agency promulgates in the future affecting registration or classification of specific pesticides, including any other regulatory restrictions imposed pursuant to section 3(d)(1)(C)(ii) of the Act.

(1) [Section 162.21(a)] *Labeling of phosphorous paste products.* This section as proposed, provided that pesticide products containing phosphorous paste would be denied registration for use in, on, or around the home. The section has been deleted from these final regulations. Pesticide products containing phosphorous paste will be reviewed in accordance with all the provisions of these regulations.

(2) Section 162.21(a) [§ 162.15(b)] *Requirement of separate registration.* (a) Several commenters asked that the provision at § 162.21(a)(1) regarding separate registrations for certain fertilizer-pesticide combinations be extended alternatively either to include all registration requirements or to encompass all fertilizer-pesticide combinations. Neither of these suggestions is acceptable. Whether separate registration of a fertilizer-pesticide combination is necessary to carry out the purposes of the Act must be determined on a case by case basis. Within the discretion of the Administrator, if the percentage of fertilizer components vary and the application rate of the pesticide remains constant, the fertilizer-pesticide combinations may be registered as a single product, provided that the range proposed would not require modification in the labeling. The intent of this Section is to lessen the administrative burden on the Agency and the registrant, where feasible.

An additional publication dealing with the registration requirements for custom blending of pesticides will be forthcoming shortly.

(b) A commenter asked that the provision of § 162.21(a)(2), permitting pigment substitution in paints without additional registration in certain instances, be extended to encompass pigment substitution in other pigment-pesticide mixtures. The Agency currently permits such pigment substitution for other products, as for example, flea collars and shelf paper, where it is determined that pigment may safely be substituted without affecting the efficacy of the product or increasing any hazard posed by the product. A new § 162.21(a)(3) has been included to clarify this policy. As with paints, the specific formulation must be submitted to the Agency and colors may be specified as additional brand names.

(3) Section 162.21(b) *Claims for Residual Bacteriostatic and/or Self-Sanitizing Activity in Labeling of Pesticide Products.* On August 23, 1973, the Environmental Protection Agency published in the FEDERAL REGISTER (38 FR 22636) a proposed Statement of Policy with respect to claims for residual bacteriostatic and/or self-sanitizing activity in labeling of pesticides pursuant to the authority of sections 3 and 25(a) of FIFRA, as amended. No final statement of policy has as yet been published in the FEDERAL REGISTER. The Agency feels that these regulations are a more appropriate place of delineating the permissible claims for residual bacteriostatic and/or self-sanitizing activity in the labeling of pesticide products. Accordingly, a new paragraph (b) has been added to § 162.21.

The proposed Statement of Policy of August 23, 1973, invited interested persons to submit written data, views or arguments. All of the written comments received were referred to the Agency's Antimicrobial Program Advisory Committee. The Advisory Committee is comprised of four representatives of the pesticide industry, four representatives of the Department of Health, Education, and Welfare, one liaison representative from the Federal Trade Commission, and three representatives and Executive Secretary from the Environmental Protection Agency. Oral views were presented to the Committee by several persons during the meetings. All written comments are on file with the Agency. Section 162.21(b) was drafted in direct response to and after consideration of all the comments received.

Section 162.21(b) provides that label claims for residual bacteriostatic and/or self-sanitizing activity will be permitted only when supported by adequate test data developed by a method which simulates the in-use situation of the product. Residual claims will be restricted to the labels of those products which will, under normal conditions of use, be exposed to conditions which are ideal for bacterial growth and activation of the residual chemical. Therefore, residual claims will not be permitted for dry treated surfaces which are likely to remain dry under normal conditions of use.

The Statement of Policy as proposed would have required registrants to comply with its provisions within 180 days of final promulgation. Several commenters argued that this requirement was unreasonable and proposed a period of 18 to 24 months. The Agency agrees that 180 days is an insufficient amount of time and will allow up to 18 months from the effective date of these regulations for compliance with § 162.21(b). In accordance with § 162.6(b)(5)(ii), if a pesticide product otherwise satisfies the requirements of these regulations and the Act, the Administrator may classify and re-register the pesticide for a reasonable period of time, pending completion of the required long term testing.

Section 162.22 *Petitions to Amend.* Several commenters argued that they have not been able to make full comment on the effect of these regulations because they were not given the opportunity to submit formal comment on the Registration Guidelines and the regulations simultaneously. EPA believes that the regulations and guidelines can be reviewed independently. Moreover, drafts of the Guidelines have been circulated among all interested parties over the past several years, including as recently as during the comment period for these regulations. Industry and environmental groups have had ample opportunity to comment on each draft of the Guidelines. The proposed Guidelines which were recently published for formal comment in the FEDERAL REGISTER are substantially the same as the last drafts which were circulated to the public.

Nevertheless in the interest of full public participation in these regulations, EPA will receive comment on those provisions of the regulations which directly relate to the Guidelines, during the Guidelines comment period. Any such comments received will be treated as petitions to amend these regulations and should fully set forth the reasons for the proposed modification and the proposed modification itself. These regulations as now published are final and will be of full force and effect 30 days after publication in the FEDERAL REGISTER. Petitions to amend these regulations will be considered as soon as possible and will not delay the effectiveness of these regulations.

PROCEDURES FOR REREGISTRATION

Prior to the effective date of these regulations, detailed procedures to be followed by applicants for reregistration of pesticide products shall be published in the FEDERAL REGISTER. This notice will address solicitation of applications for reregistration, the contents of the applications and the Agency's intended policy regarding applications for amended registration and reregistration of distributor products. Registrants are asked to await these detailed procedures before contacting the Agency regarding reregistration of a product.

Effective date: August 4, 1975.

Dated: June 26, 1975.

JOHN R. QUARLES,
Acting Administrator.